Chapter 33

DISCUSSION SUMMARY: WORK GROUP E—STRATEGIC RESEARCH PLANNING

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INTRODUCTION

Since early in Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF), it has been clear that service members in southwest Asia (SWA) are exposed to extremely high levels of geogenic airborne particulate matter (PM). Data from the Army's Enhanced Particulate Matter Surveillance Program (EPMSP), which sampled ambient PM at 15 locations over 18 months throughout SWA, indicate that ambient levels of PM in the region far exceed US Environmental Protection Agency (Washington, DC) environmental levels, National Institute of Occupational Safety and Health (Atlanta, GA) and Occupational Safety and Health Administration (Washington, DC) occupational levels, and military exposure guidelines.[1] Both peer-reviewed publications and reports in the popular press[2] have suggested that deployment to SWA might be associated with an increase in respiratory symptoms[3,4] and lung disease.[5] Concerns have also been raised both in the press and in Congressional testimony[6] that exposure to combustion products from large-scale waste burning at military facilities might play a role in the development of chronic disease. However, formal studies[6,7] have not found clear associations between disease and exposure.

The US Army Center for Health Promotion and Preventive Medicine (now the US Army Public Health Command [USAPHC; Aberdeen Proving Ground, MD]) commissioned an evaluation of the EPMSP by the Committee on Toxicology (COT) of the National Research Council (Washington, DC).[8] The US Department of Veterans Affairs (VA; Washington, DC) charged the Institute of Medicine (IOM) with providing an independent assessment of health risks associated with burn pit exposure.[9] Neither of these reviews was able to draw clear conclusions about health risks associated with exposure to ambient PM or burn pit combustion products because of numerous data gaps in both the nature and extent of exposure; and the lack of understanding of how young, fit military populations might respond to airborne hazards. However, both study groups did express concern that exposures to high levels of ambient PM, burn pit combustion products, and other types of air pollution might result in chronic or long-term disease in service members who had been deployed to SWA. The COT and IOM recommended several efforts to ascertain the prevalence, severity, and causality of service-related disease that might have resulted from exposure to airborne hazards in SWA, including more thorough and extensive environmental monitoring and studies of service members and veterans who had been exposed or not to burn pit combustion products.

To facilitate the development of a comprehensive 5-year strategic research plan to assess possible health risks associated with exposure to natural and man-made airborne hazards during deployment to SWA, approximately 20 participants in the 2012 VA/US Department of Defense (DoD) Airborne Hazards Symposium (held in Washington, DC) assembled on the second day of the symposium (as Work Group E) to discuss the substance and structure of such a plan. Participants were asked to consider a number of programmatic and scientific factors during their discussions of the strategic plan and

- identify critical research questions;
- quantify the risk associated with exposure and development of respiratory disease;
- identify enabling technologies, competencies, and infrastructure that may need to be developed or acquired to address research questions;
- prioritize research questions based on the relevance for evaluating risks and feasibility;
- maximize payoff by coordinating VA and DoD research efforts in the design and implementation of short- and long-term plans ensuring collaboration throughout;
- integrate, where feasible, toxicological, clinical, epidemiological, and modeling data to effectively address different questions or aspects of the same question;
- include veterans in appropriate stages of research ("participatory research"); and
- recognize the need for ongoing effective communications with stakeholders throughout planning and implementation of studies.

Participants were also encouraged to think beyond current research efforts that have tended to focus on pulmonary injury following inhalational exposures to PM. The work group (WG) was reminded that health risks associated with other routes of exposure, other types of hazardous material (as well as mixtures of materials), and injuries to other organ systems might also be important for evaluating both short- and long-term health risks for service members. Thus, the WG was asked to consider other routes of exposure (eg, transdermal), injuries to other organ systems (eg, cardiovascular), and exposure to gases and vapors, in addition to PM.

Although the WG did not produce a 5-year plan, exchanges among the participants revealed a number of areas of concern related to airborne hazards and suggested methods for addressing them. The themes, nevertheless, present a body of concern held by professionals in relevant fields that should prove useful to policy makers and research managers in the VA and the DoD as they develop responses to the potential airborne occupational hazards experienced by service members in SWA.

As a side note, there was a cultural difference between participants with operational military backgrounds and

participants from the research, clinical, and compensation communities. Participants from the operational world were highly focused on understanding environmental health risks with the aim of preventing injury through improved operational management, environmental risk assessment, and environmental surveillance. Other participants tended to focus on causal links between potential hazards and disease, severity of disease, and associated disability. Different perspectives were understandable, given the difference between carrying out operational activities, supplying medical care to veterans and service members, and providing compensation where appropriate.

Major areas of concern and highlights of the discussion are summarized in the next section.

OUTCOMES OF THE DISCUSSION

Prevalence and Severity of Deployment-Related Lung Disease

The fundamental issue that emerged from the conversation of the WG participants was whether or not deployed service members have had or are experiencing exposures to airborne hazards. The VA and USAPHC commissioned independent reports on health risks associated with burn pits in SWA from the IOM and the National Research Council COT on the value and quality of EPMSP. Both reports addressed evidence for associations between disease states in service members deployed to SWA. The COT[8] and IOM[9] reports, additional published data, and other data presented during the symposium provide a confusing picture of the prevalence and severity of pulmonary and other disease(s) that have been ascribed to deployment to SWA. For example, although analysis of self-reported respiratory symptoms taken from the Millennium Cohort Study[4] suggests that there may be an increase in respiratory symptoms associated with deployment, the observation does not seem to be supported by the clinical data presented by Dr Michael Morris[7] during this symposium. Case clusters of acute eosinophilic pneumonia[10] and constrictive bronchiolitis[5] have also been reported, but these involve few individuals. It has been difficult to assess to what extent these rare events might be harbingers of long-term risks or reflective of inapparent disease in the deployed cohort. A limited number of studies of the toxicity of natural PM from SWA have been performed and although these studies do not support the interpretation that the dusts are unusually toxic, the studies have all used single or short-term exposures that do not model the exposures that service members experience while deployed.[11]

The WG discussed a number of approaches to clarifying the relationship between exposures to airborne hazards and disease. These included studies of SWA populations. It is uncertain how much or what data might be extant, and it is unclear how to establish a relationship with SWA authorities that would permit either protocols relying on historical records or clinical studies. Successfully undertaking such studies might require the involvement of agencies other than the DoD and VA (eg, US Agency for International Development, Washington, DC), as well as mechanisms for providing benefit to the study population. Participants noted that, in the past, the DoD had performed studies of local populations in the region of the former Yugoslavia.

Participants were also concerned that the granularity of available exposure data was not fine enough to capture the actual exposures that service members received. Currently, exposure data are chiefly captured in terms of broad geographic localization or Military Occupation Specialty codes. In practice, in deployed settings, it is likely that neither of these variables can be relied on to capture exposure information with any degree of precision.

The WG supported continuing epidemiological survey studies through the efforts of the USAPHC,[12,13] the Millennium Cohort Study,[14] the Armed Forces Health Surveillance Center (Silver Spring, MD),[6] and the National Health Study for a New Generation of US Veterans.[15] However, because the occurrence of deployment-related disease from exposure to airborne hazards appears to be rare in the short term, a possible approach built on focused clinical studies of groups of service members or veterans reporting respiratory systems or disease might be informative for determining the range of diseases associated with deployment. A cohort of particular interest is a group of approximately 40 patients diagnosed with constrictive bronchiolitis by lung biopsy at Vanderbilt University Medical Center (Nashville, TN).[5] The limited number of known causes for constrictive bronchiolitis and the severity of the disease have made these patients a cohort of intense interest. Although a few of these patients may have been exposed to sulfur dioxide while fighting the sulfur fire at the Al-Mishraq sulfur plant near Mosul, Iraq, in 2003, the majority of them do not report exposures known to have clear associations with constrictive bronchiolitis.

However, it may be possible to capture a broader array of diseases by performing clinical follow-ups on service member and veteran participants in the Millennium Cohort Study and the National Health Study for a New Generation of US Veterans who self-report respiratory symptoms or disease. Although a number of caveats apply to both studies, their large number of participants, the mix of deployed and nondeployed present and former service members, and the ability to follow veterans over long periods would provide a strong foundation for informative epidemiological studies in their own right or for focused clinical follow-on work. Approaches that have not yet been taken but that could provide

leads to deployment-related illness include examining the reasons for service member separation and comorbidities associated with traumatic brain injury and posttraumatic stress disease. Because disease states may be progressive, it was also important to perform baseline studies of veterans that would establish the baseline health of the population.

Other populations that might prove to be sources for follow-up studies include patients within the VA medical system; firefighters who fought the sulfur fire at Al-Mishraq; and service members who were not actively involved in firefighting activities, but who were deployed within the radius of the fire's plume.

As noted previously, the toxicity of geogenic PM and burn pit combustion products have not been well studied. In particular, there is a lack of chronic studies and comparative toxicity assessment of PM from different localities. The WG considered that ascertaining the adverse outcomes resulting from exposures to these materials in animals could effectively highlight possible disease states in the service member and veteran populations.

Finally, the committee members were in accord with the IOM report[9] on burn pit exposures. Although the emphasis to date has been on exposures to geogenic dusts and burn pit combustion products, other exposures singly and in combination may also increase the risk of disease in the deployed population.

Environmental Sampling for Health Surveillance

A second major discussion theme was whether and how environmental sampling and surveillance in theater could be improved and better utilized. Whereas the current procedures have limitations and are restricted to sampling for potentially hazardous materials that are known or plausibly expected to be present, a vast amount of data is currently being gathered. Participants were concerned that these data were not readily available for data mining and decision-making because of data storage practices. Participants averred, for example, that not all data were routinely digitized. If data were more accessible, the distribution of analytes of interest could be better linked to troop movements for risk assessment and exposure evaluation. It was also suggested that increasing the availability of sampling data from previous conflicts might enhance epidemiological studies.

The discussants considered the issue of gases and volatile organic compounds that are ubiquitous in military occupational environments. Many solvents are highly volatile; and burning waste, cooking, and vehicle operation produce gases and volatile organics. Many of these chemicals have established toxicities, but are not routinely sampled. These compounds are difficult to capture in exterior environments (eg, near burn pits). There is no inventory of such compounds generated in common activities in the deployed environment, thus representing a significant data gap. With respect to burn pits, it will be difficult to generate such an inventory without better understanding the types of materials that were incinerated. Improved sampling equipment and protocols will probably be required to refine capture and analysis of these materials.

There was some discussion, as well, of whether sampling could be improved with better-trained personnel and better equipment. The value of unmanned aerial vehicles and personal sampling devices similar to radiation badges was also discussed. Although the availability of personal dosimeters is not likely to occur in the near term, the WG considered whether monitoring exposures at the small group level might be a useful intermediate term tactic. An interesting approach that was briefly considered was the use of either wild or domesticated animals present in the local environment as sentinels.

Improved Procedures and Methods for Diagnosis and Screening for Environmental Injury

A third recurrent topic of discussion among the participants was the need for improved procedures and methods for diagnosing and screening environmental, especially pulmonary, injuries. There was some question about whether there was a sufficient benefit to warrant spirometric screening for service members with conventional methods. Also, there was a question concerning whether a better solution might be the development of technology that would allow self-capture of respiratory data for frequent respiratory function testing without requiring a large increase in the number of pulmonary function technicians.

Discussants also raised the issue of whether it would be possible to develop improved diagnostic measures and tools. One aspect of this discussion was improved functional physiological testing, and another was the development of a new generation of biochemical biomarker tests in exposure and disease in blood and urine. The WG participants also suggested that there is value in archiving biosamples for both the individual health record and the historical investigation of delayed health effects. This topic flowed into a brief consideration of whether current archival procedures and technologies were adequate.

There was also a very brief consideration of whether there might be value in using genetic profiling to identify individuals at high risk for adverse responses to exposure and limiting their exposure to relevant hazards.

The WG also devoted some discussion to the appropriateness of the current generation of survey instruments for capturing exposures following deployment. There was concern that service members might not truthfully report

exposures because they feared it could affect redeployment or leave. There was also concern that service members might not recognize exposures that should be reported.

Mitigating the Risks of Exposure

The fourth topic of discussion was improvements in mitigating the risks of exposure. There was consensus that combatant commanders did not willingly make decisions that put service members at risk; but that lack of policy, planning, and training might leave them unprepared to mitigate risks to the fullest extent possible. For example, exposures to burn pits might have been avoided or reduced if the locations of the burn pits had been considered earlier during operations. Participants suggested that both improved methods for reducing the volume of the waste stream and disposing of waste will be necessary in the future because it is unlikely that the burn pits can be eliminated in the short term.

The WG also suggested that, particularly if new tools for health screening come on line, it may be necessary to update or improve training for commanders so that they can take these new data into account. A significant concern of the participants was the difficulty of predicting what the relevant exposures might be for future deployments and how to prepare to deal with them. The WG suggested that improved methods, training, and policy for proactively dealing with exposure threats were desirable.

Finally, participants proposed that it might be necessary to develop improved personal protective equipment for high-level ambient exposures, such as the airborne PM present in SWA. Available respirators are uncomfortable and clog rapidly.

Other Topics

The WG also discussed some specific issues that do not fit cleanly into the categories as previously described. These issues included research into better methods for preventing tobacco use and promoting and aiding tobacco use cessation. There was also concern that the services did not have a solid understanding of the risks and prevalence of berylliosis in service members, given the increasing use of beryllium in electronics and other materiel.

Members of the VA WG were concerned about how to integrate clinical measures into disability determinations. Appropriate biomarkers of exposure would have great utility in establishing whether disability applicants had grounds for consideration. Because disability determinations depend on how much capacity the applicant veteran has lost, there is a need to understand how the disease process affects the entire person.

SUMMARY

In general, the discussions by the WG were well-aligned with the recommendations in the IOM's *Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan*[9] (six key recommendations and discussion of current responses are included in the Attachment). Although they ranged over a wider field, they reflected the presence of operational, clinical, and exposure science experts in the WG. Perhaps the two broadest conclusions of the WG were (1) that effective resolution of the key research questions would require the cooperative efforts of the DoD and VA; and (2) that effective resolution of the question of whether respiratory or other disease(s) is associated with deployment to SWA. The deliberate pace of scientific investigation needs somehow to be accelerated, particularly when it is combined with the pace of the deliberative process in government, the risk that decisions regarding compensation and the causality of injury may be made by the court of public opinion rather than by objectively weighing the evidence. Such decisions have an impact on every phase of occupational health decision-making and affect service members and veterans in all arenas, from the development of risk mitigation strategies to compensation award.

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ATTACHMENT: FUTURE RESEARCH—RECOMMENDATIONS FROM THE INSTITUTE OF MEDICINE'S 2011 REPORT ON THE LONG-TERM CONSEQUENCES OF EXPOSURE TO BURN PITS IN IRAQ AND AFGHANISTAN

Introduction

The Institute of Medicine (IOM) made a number of recommendations for an integrated research effort ascertaining the health risks associated with burn pit exposures. They are cited herein with brief descriptions of relevant studies that could be leveraged, are in the planning stages, or are under way.

Institute of Medicine Recommendation 1

> A pilot [feasibility] study should be conducted to ensure adequate statistical power, ability to adjust for potential confounders, to identify data availability and limitations and develop testable research questions and specific objectives.[1(p126)]

A formal statement of research goals, structure, pilot, and feasibility studies will help minimize the overall risk of not achieving the stated research goals. Three studies (the US Department of Defense [DoD] Millennium Cohort Study,[2] the DoD Armed Forces Health Surveillance Center Cohort,[3] and the US Department of Veterans Affairs [VA]/DoD's National Health Study for a New Generation of US Veterans[4]) are investigating the relationship between deployment and long-term health effects, including potential respiratory effects.

The IOM recommends pilot studies to

> address issues of statistical power and develop design features for specific health outcomes.[1(p124)]

Physical examination on a population basis is necessary to determine individual variability as it relates to health outcomes, such as lung function over time. Care for veterans in the immediate postdeployment period cannot wait for long-term outcome studies to determine final disease states for those with postdeployment symptoms. Early markers of disease in the respiratory system should be a component of a research-based physical examination. Results of this research could help to inform veteran care and healthcare policy.

IOM also commented that

> More research is needed to identify useful, meaningful, reliable and implementable biomarkers.[1(p119)]

Epigenetics is an evolving discipline to detect the human effects of exposures. The VA's Million Veteran Program, an Office of Research and Development (ORD)-supported genomics research project within the Cooperative Studies Program (CSP), has the ability to administer health-related questionnaires and collect specimens. However, it is limited in its ability to understand burn pit exposures across the entire deployed population due to its nonrandom selection of participants and lack of physical examinations. The Million Veteran Program may offer insights to the background epigenetic variations as they relate to common exposures of daily nondeployed life. The CSP, which also supports Gulf War veteran studies, will be a logical resource to perform a study-by-study analysis to determine what modifications are necessary to meet gaps in burn pit (airborne hazards) research.

Institute of Medicine Recommendation 2

> An independent oversight committee … should be established to provide guidance and to review specific objectives, study designs, protocols and results from the burn pit emissions research programs that are developed.[1(p126)]

Existing independent advisory bodies may potentially provide the recommended level of external oversight. The ORD has an extensive peer-review process for the VA researchers through its standing review committees (composed of experts from inside the VA, as well as those from academia, other government agencies, and industry). These committees review research applications, specific objectives, study designs, protocols, and all other aspects of proposed research in a structure modeled after the Center for Scientific Review at the National Institutes of Health (Bethesda, MD).

In the past, various work groups (WGs) were formed to address subsets of the respiratory issue. In 2005, the Assistant Secretary of Defense for Health Affairs formed the Joint Particulate Matter Work Group to investigate the composition of particulate matter (PM) across the Central Command Area of Responsibility (CENTCOM AOR), the Middle East, thus resulting in the Enhanced Particulate Matter Surveillance Program that has been reviewed by the National Academies.[5] In 2010, the Pulmonary Work Group was formed under the auspices of the Military Operational Medical Research Program of the US Army Medical Research and Materiel Command (Fort Detrick, MD). This WG has identified research gaps and priorities in the area of toxicology, epidemiology, and clinical studies.[6] It is critical to monitor the clinical course of case series, such as the US Army Study of Active Duty Military for Pulmonary Disease Related to Environmental Dust Exposure (STAMPEDE).[7] Under the auspices of the Joint Executive Council and Health Executive Council, the DoD/VA Deployment Health Work Group continues to collaborate and support many of these activities.

Institute of Medicine Recommendation 3

> A cohort study of Veterans and active duty military should be considered to assess potential long-term health effects related to burn pit emissions in the context of other ambient exposures at the JBB [Joint Base Balad].[1(p127)]

The VA Office of Public Health is developing an overarching research study to provide continuity and resources for the extended period (likely decades) necessary to address the potential long-term health effects. This multisite study is a collaborative effort with the VA CSP and is intended to examine the health of all veterans prospectively. Ongoing studies also continue to address the research goals as a whole. Three current studies continue to evolve and focus on health concerns of Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND). Efforts of the Millennium Cohort Study,[8] sponsored by the DoD, has evolved from its Gulf War origins to include additional deployment exposure questions related to OEF, OIF, and OND. The VA is partnering with DoD on the Millennium Cohort Study to facilitate the use of VA clinical data to confirm self-reported outcomes. First, this collaboration is likely to improve the validity of the Millennium Cohort Study and improve the understanding of health effects related to deployment. Second, the VA's National Health Study for a New Generation of US Veterans[4] has completed its first data collection and is now in the analysis phase. A paper on the prevalence of respiratory conditions has been submitted for publication. Self-reported exposure questions consistent with the Millennium Cohort Study questionnaire are included. Third, the Armed Forces Health Surveillance Center (Silver Spring, MD) followed deployed personnel for 36 months.[3] Clinical diagnoses from electronic databases were used, but did not allow for adjustment of known confounders (eg, smoking). These initial postdeployment health outcome studies, as well as those conducted by the Naval Health Research Center (San Diego, CA) with cohorts from locations in the CENTCOM AOR with burn pits, were cited by IOM as evidence of feasibility. These studies are ongoing and will be continued for many years.

Institute of Medicine Recommendation 4

> An exposure assessment for better source attribution and identification of chemicals associated with waste burning and other pollution sources at JBB [Joint Base Balad] should be conducted … to help the VA determine those health outcomes most likely to be associated with burn pit exposures.[1(p127)]

Sampling and risk assessments were done at various times at Joint Base Balad (JBB), but individual sampling was not performed. The burn pit at JBB was closed in 2009 when incinerators were operational and no further real-time exposure measurements were possible. Although the IOM suggested further characterization of the JBB soil dioxin level to evaluate dispersion, soil turnover and covering have occurred, as well as a significant reduction in military presence in Iraq. The US Army Public Health Command (Aberdeen Proving Ground, MD) is currently analyzing the existing four earlier rounds of air sampling data to identify spatial and temporal trends.

Additional burn pits continue to operate in Afghanistan. DoD plans to perform personal monitoring of service members stationed in Bagram, Afghanistan. In addition, DoD plans to perform ambient monitoring for PM and volatile organic compounds. On occasion, deployed preventive medicine personnel collect ambient PM samples in and around burning operations (typically either every sixth day, or every 1 or 2 days when visiting remote forward operating bases). These data may help inform further studies on the association of exposure to airborne hazards and adverse health effects.

Institute of Medicine Recommendation 5

> Exposure assessment should include detailed deployment information including distance and direction individuals lived and worked from the JBB [Joint Base Balad] burn pit, duration of deployment, and job duties.[1(p127)]

The VA relies on DoD to provide deployment data. A recently signed DoD/VA Data Transfer Agreement will expedite the transfer of data between both organizations, and increase the timeliness and completeness of future studies.

Various respiratory exposures should be considered. Burn pit exposures may have been highest in nonveteran populations (eg, US government contractors) working in proximity to the burn pits. The exposure assessment suggested by IOM will require individuals to complete exposure assessment questionnaires with specific questions related to location, duration, and duties.

Institute of Medicine Recommendation 6

> Assessment of health outcomes is best done collaboratively using the clinical informatics systems of the DoD and VA.[1(p127)]

Current electronic health records are limited in their ability to capture exposure data and view complete healthcare outcomes across delivery systems. The VA plans to link outcome data with self-reported questionnaire data from the DoD's Millennium Cohort Study (which has a sizable veteran population). The Office of Public Health and ORD are also actively working to embed two or three VA personnel in the Millennium Cohort Study office to conduct joint DoD/VA research and provide VA chart reviews of conditions self-reported from veterans participating in the Millennium Cohort Study.

Summary

Approximately 20 participants in the DoD/VA Airborne Hazards Symposium participated in a multidisciplinary WG to formulate a comprehensive 5-year strategic research plan to assess possible health risks associated with exposure to natural and man-made airborne hazards during deployment to southwest Asia. The potential risks and solutions were sufficiently diverse that the WG did not develop such a plan. Nevertheless, deliberations of the WG converged on several areas of concern that may serve to inform research efforts by the VA and DoD. These areas included a very incomplete understanding of the prevalence and severity of deployment-related lung disease, thus

- improving the scope and effectiveness of environmental sampling for health surveillance,
- improving procedures and methods for diagnosis and screening for environmental injury, and
- mitigating the risks of exposure.

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