

Assessment of the
Department of Veterans Affairs
Airborne Hazards and Open Burn Pit
Registry

Presentation to the Research Advisory
Committee on Gulf War Veterans' Illnesses
David Savitz

Origin of the Study

Public Law 112-260, §201 directed the Department of Veterans affairs to establish and maintain a registry for service members who may have been exposed to toxic airborne chemicals and fumes generated by open burn pits.

The law also called for an independent scientific organization to prepare a report addressing issues related to the establishment and conduct of the registry and use of its data.

Statement of Task from the VA

- Solicit veteran input; and
- Provide methodological recommendations on how to best ascertain and monitor the health effects of exposure to open burn pits and other potential airborne hazards during deployment.

Statement of Task, continued

Evaluate and offer recommendations on:

- how to categorize the self-reported exposures in the AH&OBP Registry,
- changes to the current information collection instrument, and
- methodological approaches to the analysis of these data.

Statement of Task, continued

- associations of self-reported exposures with self-reported health conditions,
- associations of self-reported exposures with Veterans Health Administration health care experience, and
- how registry participants differ in demographic or exposure status from non-participants

Statement of Task, continued

- how best to use the registry's self-reported data to benefit active-duty military personnel and veterans who were exposed to burn pit emissions

Committee Members

David A. Savitz (*Chair*), Vice President for Research, Professor of Epidemiology, and Professor of Obstetrics and Gynecology, Brown University

Vinícius C. Antão, Director of Patient Registries, Healthcare Research Institute, Hospital for Special Surgery

Jane E. Clougherty, Associate Professor and Director of Exposure Science, University of Pittsburgh

Montserrat Fuentes, Dean of College of Humanities and Sciences, Virginia Commonwealth University

Richard A. Kulka, Consultant, Richard A. Kulka Consulting

Frances Murphy, President and CEO of Sigma Health Consulting, LLC

Committee Members, continued

Cecile S. Rose, Professor of Medicine in the Division of Environmental and Occupational Health Sciences, National Jewish Health

Armistead G. Russell, Howard T. Tellepsen Chair and Regents' Professor, Georgia Institute of Technology

David H. Trump, Chief Deputy Commissioner for Public Health and Preparedness, Virginia Department of Health (retired)

Joyce S. Tsuji, Principal Scientist, Exponent

Mark J. Utell, Professor of Medicine and Environmental Medicine, Director of Occupational and Environmental Medicine, University of Rochester Medical Center

Information-Gathering Workshop

- Presenters included
 - researchers who conducted studies of in-theater exposures and health outcomes
 - physicians providing health care to veterans
 - veterans and veterans service organizations
- Input gave the committee insight into veterans experiences and informed their discussions throughout the study process.

Summary of Conclusions

There are inherent limitations in an environmental health registry that relies on voluntary participation and self-reported data

Registries are not a substitute for a well designed and executed epidemiologic study of possible associations between exposures and adverse health outcomes

Such registries may be useful for documenting the experience and concerns of the participants, and to generate hypotheses that would stimulate and inform research using more rigorous approaches

Environmental Health Registries

Advantages

- Useful for collecting and maintaining data on a group of people characterized by a specific disease, condition, exposure, or event to facilitate research, monitor health, or provide information to registrants
- Quicker and less expensive than research
- Allows for ascertainment of multiple exposures and health outcomes on a defined population

Environmental Health Registries

Disadvantages

- Voluntary participation and self-reported information limit scientific value (selective participation, faulty recall, inaccurate information)
- Poor sources for generating normative data on population of interest, vulnerable to biased estimates of exposure-disease associations

AH&OBP Questionnaire

- VA required to establish and maintain a registry “not later than one year” after enactment
- Problems in resulting questionnaire result in part from the inherent weaknesses of voluntary, self-report registries
- Exacerbated by flaws in the registry’s structure and operation, choice and format of some questions
- High percentage (about 40%) of respondents who initiated but did not complete the questionnaire and the number of questions with substantial nonresponse are indicative of problems with the data collection methods

Data Provided for Analysis

- All completed questionnaires (N=46,404) received between June 19, 2014 and July 31, 2015
- Gulf War Oil Well Fire Smoke Registry for information on 1990-1991 Gulf War veterans; and
- Contingency Tracking System data for post 9/11 veterans

No personally-identifiable information was provided

These data represent approximately 1.0% of Gulf War veterans and 1.7% of post-9/11 veterans eligible to participate in the Registry

Limitations of Data Provided

No mortality data provided

No data on health care use or medical records through VA or DoD were provided, preventing the committee from addressing VA's request to examine associations of self-reported exposures with Veterans Health Administration (VHA) health care experience

Findings from Data Analyses

Respondents spent an average of 14.5 months deployed

75% reported more than one eligible deployment, with an average of 4.4 deployments.

Respondents were not representative of the eligible population for nearly all demographic and military characteristics available for comparison

No external comparison populations were determined to be appropriate to registry participants

Analysis of Exposure Data

No objective exposure data were available.

Multiple approaches were used to analyze the exposure data given the uncertainty

The committee created exposure potential measures for each of the six main exposure sources as collected by the questionnaire as well as a cumulative exposure measure

- proximity to burn pits
- diesel/exhaust/fuel
- construction
- soot for 1990-1991 Gulf War veterans
- dust
- combat

Conclusions on Exposure Data

Exposure data are of insufficient quality or reliability to make them useful beyond general assessment of exposure potential

Supplementing these data with other information might help to identify individuals or groups that experienced greater or lesser exposures to specific pollutants and facilitate more detailed assessments of health outcomes

Multivariate Analysis Results

Participants who reported higher levels of essentially all exposures tended to also report a higher prevalence of essentially all adverse health outcomes

The committee's analyses suggest that such results may be a consequence of the population's selection and the limitations of the self-reported exposure and disease data, not as evidence for a causal association

The committee emphasized that it would have reached this same determination had the analyses found no associations between the exposures and health outcomes

Maximizing Registry's Value

Make it a means for the eligible population to document their concerns over health problems that may have resulted from their service and bring those concerns to the attention of VA and their health care providers

Supply VA with a list of persons who are interested in burn pit exposure issues for ongoing communication

Generate data on the prevalence of health problems in the respondents that might stimulate research using more sophisticated approaches

Questionnaire Recommendations

The committee recommends that VA eliminate the questionnaire sections addressing locations of previous residences (Section 4), non-military work history (5) and home environment, community, or hobbies (6)

Eliminating these sections would make the questionnaire easier and faster to complete, would better focus it on the needs of the eligible population, and remove questions that do not contribute to the registry's attainable goals

Questionnaire Recommendations

Clarify the intent and purpose of the registry

Develop a specific plan for integrating relevant VA and DoD data with the registry's data to reduce participant burden

Increase data quality by restructuring questions to minimize recall and other biases

Improve the usefulness of the registry as an information source for health care professionals and researchers

Questionnaire Recommendations

Provide alternative means of completing the questionnaire such as a mail-in form or computer-assisted phone interview

Engage external survey experts experienced in Web-based instruments in any restructuring of the registry questionnaire

Data Analysis Recommendations

Evaluate whether and how registrants who did not complete the questionnaire differ from those who did, analyze the determinants of non-completion, and use this information to formulate strategies to encourage registrants to finish and submit their responses and improve the completion rate for future participants

Data Analysis Recommendations

The committee recommends that other means for evaluating the potential health effects associated with airborne hazards and open burn pit exposures be developed, such as a well designed epidemiologic study

Registry Messaging Recommendation

Be explicit about the limitations on the ability of the Registry to generate valid scientific information that can be used directly to improve VA health and benefits programs or inform treatment of individuals potentially exposed to burn pits or other airborne hazards to ensure that participants and others do not form unrealistic expectations about the value of participation or capabilities of the registry

Clinical Use of Registry Data Recommendation

Develop a concise version of participant's questionnaire responses focused on information that would be most useful in a routine clinical encounter and make it available for download

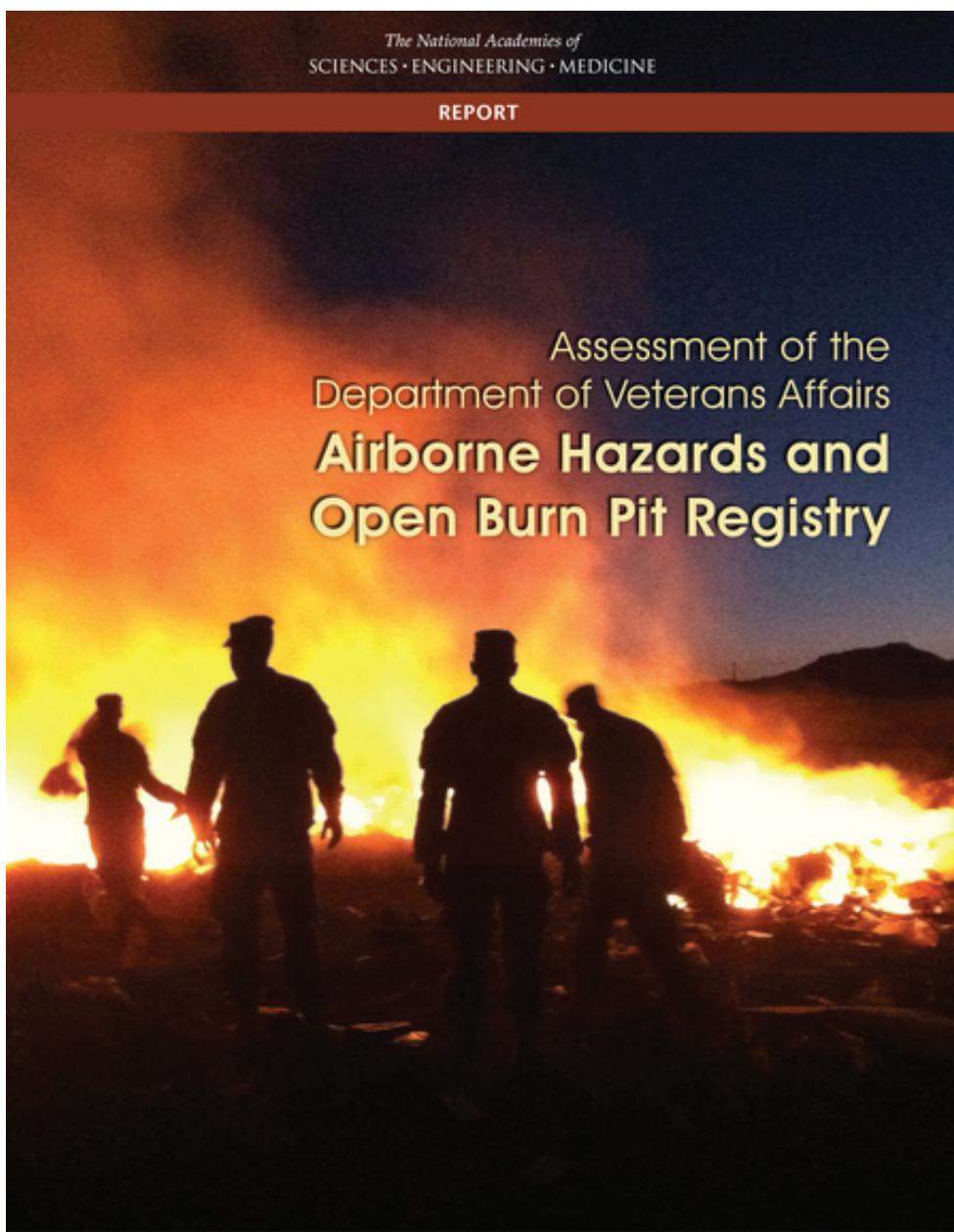
Clinical Evaluation Recommendation

Continue efforts to make it easier for participants to schedule and get the optional health examination offered as part of the AH&OBP Registry—such as targeted follow-up of respondents who indicate interest—and investigate the reasons why such a small percentage of respondents who indicate interest in an exam (~2.5%) request one

Closing Observations

All parties—service members, veterans, and their families; VA; Congress; and other concerned people—would benefit from having a realistic understanding of the strengths and limitations of registry data so that they can make best use of them and, if desired, conduct the kind of investigations that might yield salient health information and improve health care for those affected

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For more information

Online information on the study may be found at
nationalacademies.org/BurnPitRegistry

The report may be read online and downloaded in digital form (at no cost) at
www.nap.edu/catalog/23677/assessment-of-the-department-of-veterans-affairs-airborne-hazards-and-open-burn-pit-registry

The study's email address is
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