

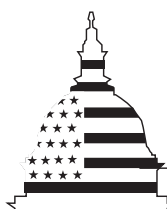
GAO

Report to the Chairman, Subcommittee
on National Security, Veterans' Affairs
and International Relations, Committee
on Governmental Reform, House of
Representatives

January 2000

GULF WAR ILLNESSES

Management Actions Needed to Answer Basic Research Questions



G A O

Accountability * Integrity * Reliability

Contents

Letter		3
Appendixes		
	Appendix I: Research Objectives Identified by the Research Working Group of the Persian Gulf Veterans' Coordinating Board	26
	Appendix II: Reports Received and Released by the Office of the Special Assistant Under Research Contracts Examined by GAO	28
	Appendix III: Sample Working Case Definitions Describing Symptoms Experienced by Gulf War Veterans	31
	Appendix IV: Comments From the Department of Defense	32
	Appendix V: Comments From the Department of Veterans' Affairs	46
	Appendix VI: Comments From the Centers for Disease Control and Prevention	53
	Appendix VII: GAO Contacts and Staff Acknowledgments	56
Related GAO Products		58



United States General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-282454

January 6, 2000

The Honorable Christopher Shays
Chairman, Subcommittee on National Security,
Veterans' Affairs, and International Relations
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

Many of the approximately 700,000 veterans of the Persian Gulf War have complained of illnesses since the war's end in 1991, and over 10 percent have sought and completed health examinations through the Department of Veterans' Affairs or Defense. Some fear they are suffering from chronic disabling conditions because of wartime exposures to one or more agents with known or suspected health effects. In response to these concerns, the government has funded research, investigation, and information activities through agencies such as the Departments of Veterans' Affairs, Defense, and Health and Human Services, which are represented on the Persian Gulf Veterans' Coordinating Board, the body that coordinates the federal response to Gulf War veterans' illnesses.

As requested, we identified expenditures on these efforts and evaluated their results. Specifically, our objectives were to describe

- the amount of money that these three departments spent on research and investigation of Gulf War veterans' illnesses and health concerns in fiscal years 1997 and 1998, including current and projected spending by the Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses;
- the productivity of this research spending, including the extent to which the Coordinating Board has determined that federal research objectives have been satisfied, and the extent to which the research has resulted in peer-reviewed publications and the identification of the causes or successful treatments for Gulf War veterans' illnesses;
- the extent of coordination between the Research Working Group of the Coordinating Board and the Office of the Special Assistant for Gulf War Illnesses; and
- the Office of the Special Assistant for Gulf War Illnesses' contract management.

Results in Brief

During fiscal years 1997-98, the Departments of Defense, Veterans' Affairs and Health and Human Services spent more than \$121 million on research and investigation of Gulf War veterans' illnesses, with DOD spending more than \$112 million of that total. These funds supported a growing catalog of research and investigatory efforts intended to address both veterans' health concerns and their questions about hazards encountered in the conflict. The Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses spent the majority of the federal research and investigatory funds we identified, about \$65.3 million in fiscal years 1997 and 1998, with another \$65.4 million in spending planned for fiscal years 1999 and 2000.

Basic questions about the causes, course of development, and treatments of Gulf War veterans' illnesses remain unanswered. As of November 30, 1999, the Research Working Group of the Persian Gulf Veterans' Coordinating Board had not published an assessment of the extent to which the research program had answered the major questions it identified as research objectives in 1995, and no date had been set to publish such an assessment. By the end of 1998, among the 151 research projects monitored by the Group, 117, or 77 percent, were recorded as ongoing, including 29, or 47 percent, of the 62 that were scheduled for completion by that time. Among those that were not recorded as complete at the end of 1998, about one-third were later completed and the remaining two-thirds had their estimated completion dates extended. Group officials attributed the extensions either to provisions to collect or incorporate additional data or to unanticipated delays, such as difficulty in securing approval to collect data or in locating and recruiting veteran participants. Augmenting the research monitored by the Group, DOD's Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses had received 19 of the 20 reports due from its major research contractors by late 1999, with 6 publicly released and the remainder largely in various stages of interagency review. Fourteen reports had remained in draft or review status for a year or longer.

While federally sponsored studies have resulted in some descriptive information concerning veterans' symptoms, many basic questions (such as the numbers of veterans with unexplained symptoms and the course of their illnesses over time) remain. Answers to more complex questions about the potential cause(s) of veterans' unexplained symptoms have been difficult to derive in part because problems in identifying veterans' specific exposures persist. In addition, no working case definition or set of

definitions of illnesses affecting veterans has been endorsed by the Group. Perhaps because analytic epidemiological research depends heavily upon exposure data and/or case definition, completed epidemiological research, which comprises a large portion of the research portfolio, has been less likely than other types to result in peer-reviewed publications and most of these studies have been descriptive. Although the question of causation is unresolved, in the interest of assisting ill veterans, the Department of Veterans' Affairs has begun recruiting patients for trials of antibiotic and exercise-behavioral treatments for a set of veterans' unexplained symptoms.

Although the Office of the Special Assistant for Gulf War Illnesses expends more than half of the federal funds supporting research and investigation into Gulf War veterans' illnesses, its activities are not effectively coordinated with those of the Research Working Group. According to officials from both organizations, the Office of the Special Assistant's activities involve investigations, rather than research, and therefore are not subject to coordination. However, the Group considered some of the Office's activities to involve research and expressed concern about the lack of an external review process. The weak coordination between the Group and the Office increases the potential to miss opportunities to leverage ongoing and completed work by other agencies, and we found a few examples of such problems.

The Office rapidly developed relationships with various contractors to support its mission. However, two of the largest task orders were awarded improperly, and the Office discouraged competition for another task order by specifying a preferred vendor. Because the Office is likely to continue to spend a significant part of its budget on support contracts, it needs to insure that its contracts fully comply with applicable requirements.

We are making recommendations to improve federal efforts to assess and conduct research, coordination between the Office and the Group, and the Office's arrangements with its support contractors.

Background

Several federal agencies and offices have generated and coordinated responses to veterans' complaints of illnesses following the Gulf War. These have included the Departments of Defense (DOD), Health and Human Services (HHS), Veterans' Affairs (VA), and Energy, the Central Intelligence Agency, the Environmental Protection Agency, the National Security Council, and the Office of Management and Budget.

The formation of the Persian Gulf Veterans' Coordinating Board (PGVCB) was announced in early 1994 for the purpose of coordinating federal research and other activities in response to illnesses reported by Gulf War veterans. This body, which is co-chaired by the Secretaries of Defense, Veterans' Affairs, and Health and Human Services, comprises working groups on research, clinical issues, and compensation. The PGVCB Research Working Group (RWG), which has no budgetary authority, does not directly manage or distribute research funds. It describes its responsibilities as (1) assessing the state and direction of research and identifying gaps in factual knowledge and conceptual understanding, (2) identifying testable hypotheses and potential research approaches, (3) reviewing research concepts as they are developed, (4) collecting and disseminating scientifically peer-reviewed information, and (5) insuring that appropriate peer review and oversight are applied to research the government has conducted or sponsored.

Within DOD, initial efforts to respond to Gulf War veterans' complaints were managed by the Assistant Secretary of Defense for Health Affairs. In November 1996, following worsening public relations, management of these efforts was transferred to the newly created Office of the Special Assistant for Gulf War Illnesses (OSAGWI), which became responsible for oversight of DOD's efforts regarding illnesses being experienced by Gulf War veterans. OSAGWI reported directly to the Deputy Secretary of Defense. The Assistant Secretary of Defense for Health Affairs continued to be responsible for managing and coordinating related health programs, while DOD's medical research efforts were managed largely by the Undersecretary of Defense for Acquisition and Technology and the Army Medical Research and Materiel Command. DOD established OSAGWI to restore public confidence in DOD's efforts to deal with Gulf War illnesses issues. OSAGWI has focused its efforts on (1) establishing effective two-way communications with veterans and veterans' groups, (2) investigating and reporting on incidents of possible chemical warfare agent exposures, and (3) applying lessons learned from the Gulf War experience to better protect U.S. servicemembers on a contaminated battlefield.

The efforts of the various federal agencies have been met with skepticism on the part of some veterans. This skepticism was fueled by the delay, until 1996, in acknowledging potential exposures to low levels of nerve agent at a munitions dump in Khamisiyah, Iraq, during postwar demolition activities. Additionally, veterans were upset by DOD's and VA's initial emphasis on stress as a potential explanation for their symptoms.

Congressional oversight of DOD's and VA's efforts has identified problems in the agencies' clinical monitoring of veterans' conditions and inaccuracies in agency statements about veterans' potential exposures.

Spending on Research and Investigation of Veterans' Illnesses Is Concentrated Within DOD

During fiscal years 1997 and 1998, HHS, DOD, and VA reported total expenditures of at least \$121.3 million on research and/or investigation of Gulf War veterans' illnesses.¹ These expenditures included \$112.4 million in DOD funds (\$65.3 million for OSAGWI and \$47.1 million for non-OSAGWI expenditures), \$7.2 million for VA, and \$1.6 million for HHS.² These amounts excluded expenditures on examination and clinical care of ill veterans during this time period.

Because OSAGWI managed the majority of DOD's research and investigation expenditures, it was the single largest component of the federal research and investigatory effort to respond to veterans' concerns. The remainder of DOD's spending was attributed to internal and external, DOD-sponsored research efforts catalogued by the RWG.

¹The RWG records funds expended by VA, HHS, and DOD based on the year in which they were appropriated. Because these appropriations can be spent over 2 years, RWG data for the most recently reported fiscal year (1998) were not necessarily a complete representation of final spending for that fiscal year. For this reason, fiscal year expenditures, which were provided in December 1998, are likely to have increased during fiscal year 1999.

²These figures do not add to \$121.3 million because of rounding. The costs for VA studies do not include overhead costs because indirect costs are included under VA's medical care appropriation. Similarly, the majority of HHS' expenditures represent direct costs only. DOD's non-OSAGWI spending does not include overhead costs for intramural studies but does for extramural ones. In addition, the numbers reported for OSAGWI include overhead costs and some spending on veteran outreach.

OSAGWI was established in November 1996, when a staff of 110 and an annual budget of \$11.4 million were projected. The Office later grew to a staff of slightly over 200, spending more than \$65 million across fiscal years 1997 and 1998, and planning expenditures of \$35.9 million in fiscal year 1999 and \$29.5 million in fiscal year 2000.³

OSAGWI categorizes its spending as research or support. During fiscal years 1997-98, OSAGWI spent \$13.3 million, or 20 percent of its expenditures, on instruments it characterized as research contracts and another \$47.1 million, or about 73 percent of its expenditures, on instruments it characterized as support contracts. The remaining funds, about 7 percent of OSAGWI spending, covered overhead, travel, conferences, computer equipment, and miscellaneous other expenses. Many of its support costs are difficult to separate from research and investigation expenditures. For example, the objectives of OSAGWI's support contracts (\$21 million) with one contractor—BDM International—include obtaining, documenting, and analyzing information potentially related to Gulf War illnesses; documenting the data and analysis in databases and other forms of storage; developing questionnaires and surveys to collect data; rapidly creating data analysis tools to aid in analysis efforts; and developing and producing case studies.

Basic Questions About Causes, Course, and Treatment of Veterans' Illnesses Remain Unanswered

The RWG has not assessed the extent to which the research agenda has satisfied the objectives it identified in 1995. The majority of federal research projects remain ongoing or in review. Problems identifying valid data on veterans' exposures persist, and basic questions, such as how many veterans have unexplained symptoms and whether those who have received care in VA facilities are getting better or worse, remain unanswered.

³Although OSAGWI officials are seeking the guidance of the Special Oversight Board on DOD Investigations of Chemical and Biological Incidents to determine what portion of its investigation work should continue and how it should draw down the Office, the Office is incorporated in DOD's budget through fiscal 2005, with twice the number of investigations ongoing as have been completed.

The Extent to Which Research Objectives Have Been Met Has Not Been Assessed

In April 1999, PGVCB officials told us they had not finished assessing the government's progress in answering the 21 major questions that the RWG had identified in 1995. As detailed in appendix I, these research objectives include questions about the prevalence of various health problems and exposures among the veteran population and the way the prevalence differs between Gulf War veterans and "appropriate control populations." With regard to exposure, the research objectives cover *Leishmania tropica* (a type of parasite), petroleum, petroleum combustion products, specific occupational/environmental hazards, chemical agent, pyridostigmine bromide, and psychophysiological stressors. With regard to veterans' health status, the research objectives cover the prevalence among veterans and appropriate control populations of symptoms, symptom complexes, illnesses, altered immune function or host defense, birth defects, reproductive problems, sexual dysfunction, cancer, pulmonary symptoms, neuropsychological or neurological deficits, psychological symptoms or diagnoses, and mortality. Questions about exposure to low levels of nerve agent were added in 1996, when DOD acknowledged that U.S. troops might have experienced such exposures during postwar demolition activities at Khamisiyah.

The research questions incorporate input from HHS, DOD, and VA but do not formally constrain the research funded by these agencies. Asked to identify which of the 21 research objectives had been satisfied by late 1998, RWG officials wrote, "Answers to some of the research questions contained in the Working Plan have been achieved to a greater degree of satisfaction than others. However, at this time, it is accurate to say that no research question has been answered to the extent that additional research would not be able to shed more light on the question." In late 1998, an RWG official noted that a draft analysis of research results as they relate to these questions was anticipated in late spring or early summer 1999 in preparation for publication of a revised working plan for research on Gulf War Veterans' illnesses, but no deadline had been established for publishing this analysis and no such analysis had been published as of June 1999. While DOD noted that the analysis was in progress, it had not been completed or a deadline established for its publication when DOD and VA submitted their comments on our draft report in August and September 1999, respectively.

Return on Research Investment Accruing Slowly

Spending on research was spread among various projects catalogued by the PGVCB's Research Working Group and an additional set of projects

sponsored by OSAGWI. While findings from this work are beginning to accumulate, most of it is ongoing or in review.

Research Catalogued by RWG

Although the research portfolio monitored by the RWG includes over 50 projects that began in 1994 or earlier, only 34 of the 151 projects, or 23 percent of those catalogued by the RWG, had been reported complete as of December 1998. This was 53 percent of the 62 that were scheduled for completion by that time. Among the 47 percent of this group that were not complete in December 1998, about one-third were later completed and the remaining two-thirds had their estimated completion dates revised (with extensions varying from a few months to 10 years). RWG officials attributed the extensions either to efforts to collect or incorporate additional data or to unanticipated delays, such as difficulties in securing approval to collect data or problems in locating and recruiting veteran participants.⁴ The officials identified four instances in which additional funds had been provided. For example, the Centers for Disease Control's health assessment of Persian Gulf War Veterans from Iowa was extended to 2000 to provide for additional follow-up of the survey sample. Similarly, DOD has committed to fund two projects for the Army's Center for Health Promotion and Preventive Medicine until 2003 and 2006.⁵

⁴For example, some projects experienced delays in approval of their plans by institutional review boards while others experienced difficulty in recruiting subjects. Some survey efforts found that it was more difficult than anticipated to track veterans' whereabouts since the war.

⁵Funding is extended through 2006 for the Kuwait Oil Fires Troop Exposure Assessment Model, a project responding to P.L. 102-190 by characterizing the potential carcinogenic and noncarcinogenic health risks to U.S. military personnel exposed to the environment affected by the oil well fires during and after Operation Desert Storm. Funding is extended through 2003 for the Persian Gulf Veterans Health Tracking System, which is intended to characterize exposures (other than airborne contaminants from oil well fires) experienced by U.S. military personnel during Desert Storm and to assess the potential health risks/consequences of those potential exposures.

By June 1999, PGVCB reported only 1 of the 13 primary research areas, leishmaniasis, had a majority of projects complete (four of seven).⁶ In one research area—treatment—no projects had yet been finished.

Among the 23 percent of federal research projects into Gulf War veterans' illnesses that were completed by December 1998, about two-thirds (22 of 34) had resulted in at least one article published in a peer-reviewed journal. (We focused on this outcome because publication in a peer-reviewed journal was suggested as a surrogate marker for research quality in early interviews with RWG officials and because publication in this form insures more widespread access to research findings.) Some of the other completed projects have had findings released in the form of technical reports or summarized in an annual report issued by the RWG. Additional peer-reviewed publications have been issued from projects that are still ongoing.

Research Expenditures Managed by OSAGWI

Five key contractors accounted for about 72 percent of the \$13.3 million that OSAGWI attributed to spending on research contracts in fiscal years 1997 and 1998. We reviewed the status of deliverables under their contracts to determine whether they had been received in a timely manner and had been released to the public. We focused on timely provision of deliverables as a basic measure of contractor performance and on release of deliverables as an indicator of effectiveness, since the contracts were often for developing public information and doing so was a major part of OSAGWI's mission. As of December 1999, OSAGWI (or the responsible element at DOD) had received 19, or 95 percent, of the 20 products due from the 5 research contracts. Among those products received, 6 had been released to the public, with the remainder largely in various stages of interagency review when we ended our work in December 1999. Fourteen products had remained in review or draft status for a year or longer. Appendix II contains detailed information on the research contracts we examined, including the contractor, the contract amount, the titles or topics of deliverables, and the deliverables' status (i.e., whether they were due at the time of our review, had been received, and/or released, what

⁶The RWG cataloged the federal research portfolio by primary research topic in March 1998. At that time, there were 121 (instead of the current 151) federally sponsored research projects. Because 30 research projects that began after March 1998 were not categorized by the RWG into primary research topics, our analysis by primary research topic includes only the 121 that had been categorized. See the RWG's report entitled *Annual Report to Congress: Federally Sponsored Research on Gulf War Veterans' Illnesses for 1997*, March 1998.

form they were in at receipt, what was the date of the earliest known receipt, and whether they had been released).

With respect to other products of OSAGWI's spending, including nonresearch spending, by January 1, 1999, OSAGWI had issued 13 case narratives (accounts of particular incidents during the war), 2 environmental exposure reports, and 4 information papers.⁷ Work on an additional 26 case investigations was ongoing.⁸ As of December 3, 1999, 1 additional case narrative and 3 additional information papers had been issued.

⁷Other accomplishments cited by OSAGWI officials in hearings before the Senior Oversight Panel on DOD Investigation of Chemical and Biological Incidents (held Nov. 19-20, 1998) included visiting five bases, answering 3,000 hotline calls, and responding to 5,000 e-mail inquiries. Additional veterans were contacted via the Office's programs to notify veterans of potential exposures or survey veterans on particular topics.

⁸For a review of OSAGWI's investigatory activities, see *Gulf War Illnesses: Procedural and Reporting Improvements Are Needed in DOD's Investigative Processes* (GAO/NSIAD-99-59, Feb. 26, 1999).

Problems in Identifying Valid Exposure Data Persist

Absence of agreement or valid data on veterans' wartime exposures has presented formidable obstacles to researchers in developing definitive information about the causes of veterans' illnesses. Although the nearly half of studies that are epidemiological depend to some extent on the use of exposure data, researchers continue to face difficulties in assessing and validating veterans' exposures. These difficulties led us to conclude in our 1997 report that the many epidemiological studies being sponsored would not provide definitive information on the causes of veterans' illnesses.⁹ Proceedings of conferences on federally sponsored research also document that researchers are experiencing increasingly difficult problems in soliciting reliable self-reported data on exposures as time from the original events increases.¹⁰ Because of such problems, the likelihood of misclassifying persons who received no exposure as having had some or significant exposure (or vice versa) will increase, reducing the capacity of data analyses to identify associations between exposures and health outcomes. Perhaps as a result, completed research projects classified as epidemiological had a lower rate of publication in peer reviewed journals than other types of federally sponsored research.¹¹

To begin to identify the causes of an unexplained illness, epidemiological researchers normally define a set of criteria, known as a case definition, that can be used to separate persons who have the condition from those who do not. This permits researchers to look into differences in their histories to gain insight into what may have caused their illness. However, no such working case definition or set of such definitions that might focus federal research has been endorsed by the Research Working Group. Working case definitions of unexplained illness among veterans that have been proposed by individual researchers have been similar to one another in emphasizing unexplained fatigue, neurocognitive complaints, and

⁹*Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed* (GAO/NSIAD-97-163, June 23, 1997).

¹⁰See the RWG, PGVCB, *Proceedings: Conference on Federally Sponsored Gulf War Veterans' Illnesses Research*, June 17-19, 1998 and June 23-25, 1999.

¹¹Of the 22 completed research projects classified as epidemiological, 12, or about 55 percent, had resulted in publication of an article in a peer-reviewed journal. By way of comparison, 83 percent (10 of 12) of the completed nonepidemiological projects had results published in such journals. (We include projects originally classified by the RWG as clinical epidemiology as well as those projects classified as epidemiology in this total; after we recommended a shift from epidemiological research in June 1997, the RWG reclassified studies formerly designated clinical epidemiology as clinical research projects).

musculoskeletal complaints, symptoms reported more commonly by Gulf War veterans than by veterans of the same era who were deployed elsewhere (see app. III).

Descriptive Information Concerning Veterans' Symptoms Exists, but Many Basic Questions Remain Unanswered

The government has had some success in cataloging data on the illnesses suffered by Gulf War veterans. DOD and VA registries gather such information, and studies have been funded to collect data on veterans' symptoms. However, owing to the data collection formats used in the registry process and the self-selection of registry participants, the registries are not optimal sources of information regarding the prevalence of various symptom clusters among veterans, making it difficult to know which of the various case definitions or symptom groups deserve closer examination. For example, these registries are unlikely to record sufficient data to determine whether a veteran meets criteria for multiple chemical sensitivity or chronic fatigue syndrome, for which recognized case definitions exist, but not standard diagnostic categories, as represented by international disease classification codes. Some federally sponsored research, notably VA's National Health Survey, might be able to clarify this issue, but descriptive data from the survey remained unpublished at the close of our review.

Although some progress has been made in cataloging veterans' illnesses, the results generally describe only what illnesses a veteran was suffering from at a particular point in time. As a result of this and the limitations of the DOD and VA registries, several basic descriptive questions remain unanswered. For example, the Special Investigative Unit of the Senate Veterans' Affairs Committee and others have identified such open questions as the following:

- How many of those veterans who have been examined have unexplained illnesses or symptoms?
- How many of those veterans are also receiving compensation for that condition?
- How many are receiving health care?
- What treatments have they received?
- Are those who have received care in VA facilities getting better or worse?

Some data that might be helpful in answering such questions are being collected, but an analysis of these data was not available at the close of our review. An HHS-sponsored project, which began in 1997, is assessing the

persistence and stability of veterans' symptoms over time. This study is planned to end in 2000. In addition, VA and DOD are recruiting patients for cooperative trials of antibiotic and exercise-behavioral treatments for a broad set of veterans' unexplained symptoms. However, perhaps because there is little understanding of the physical causes underlying veterans' symptoms, VA and DOD officials note that the treatments to be used in these trials are expected only to ameliorate symptoms, not to eliminate them.

RWG and OSAGWI Activities Not Effectively Coordinated

OSAGWI's activities have not been effectively coordinated with those of the RWG in order to maximize the efficient use of resources. We found conflicting information about the nature of OSAGWI's work and whether it should be coordinated. Specifically, RWG and OSAGWI officials told us that OSAGWI's activities involve investigations, not research, and therefore are not subject to coordination. However, in an August 1997 letter to OSAGWI, the RWG raised questions about the methodologies of three OSAGWI-sponsored studies and expressed concern over the lack of any external review process for these studies and for OSAGWI's research efforts in general. OSAGWI pursued these studies, but it has not published their findings. The lack of effective coordination between the RWG and OSAGWI increases the potential to miss opportunities to leverage ongoing and completed work by other agencies.

Other examples illustrate the need for better coordination. For example, in January 1998, the National Academy of Science's Institute of Medicine presented a proposal to VA, which was funded under a congressional mandate, to pursue studies at a projected cost of \$1.25 million to "comprehensively review, evaluate and summarize the available scientific and medical information regarding the association between exposures during the Persian Gulf War and adverse health effects experienced by Persian Gulf War veterans." However, in 1997, OSAGWI had contracted with RAND at a cost of more than \$1.5 million for "the preparation of literature reviews of key possible causal hypotheses of GWI."¹² The Institute's assessments regarding the links between exposures and health outcomes must be based, at least partly, on the review of relevant literature, and RAND's identification of this literature has required, at least, some assumptions regarding potential exposure scenarios. Thus, it should

¹²OSAGWI eventually authorized RAND work valued at \$3.2 million.

have been possible to use RAND's ongoing work for the Institute study, and better coordination of these two efforts might have saved both time and money. When we interviewed Institute staff in June 1998, they were generally aware of RAND's plan to perform literature reviews, but they were not familiar with the content of RAND's work, noting that none of it had been released. While RAND did seek approval of a list of scientific peer reviewers for its work from Institute officials, in the absence of coordination mechanisms, these two efforts were pursued independently.

Similarly, at least three reviews of the health effects of depleted uranium have been commissioned within a few years – one by each agency represented on PGVCB. HHS' Agency for Toxic Substances and Disease Registry first released a toxicological profile for uranium in 1989 and issued an updated draft toxicological profile on uranium (including depleted uranium) on October 17, 1997. This draft, prepared by the Research Triangle Institute, incorporated a plain-language public health statement and reflected the Agency's assessment of all relevant toxicological testing and information that had been peer-reviewed. In addition, at OSAGWI's request, RAND performed a review of the scientific literature regarding the health effects of depleted uranium. Finally, IOM will conduct such a review as part of its work for VA. The need for the additional review of depleted uranium by RAND, which was submitted in August 1998, after the Agency had issued its draft, is questionable.

Contracting for OSAGWI Support Services Was Flawed

OSAGWI spent more than \$47 million in fiscal years 1997 and 1998 on its support contracts. We reviewed four support agreements, which made up more than 91 percent of OSAGWI's support spending, and found problems with several of the task orders. Specifically, two of the largest task orders were awarded improperly, and OSAGWI discouraged competition on another by naming a preferred vendor.

Improper Task Orders

OSAGWI's support arrangements consisted largely of task orders under multiple-award contracts of other agencies and offices. OSAGWI's largest support arrangement was based on two improper task orders awarded to BDM. OSAGWI officials noted that they were directed to establish the Office with all possible speed and explained that they anticipated relying heavily on contractors for support. As part of addressing this need, an initial task order covering a broad range of services was awarded to BDM under a National Guard Bureau (NGB) multiple-award task order contract for information technology services.

The BDM task order describes its objectives as including, but not limited to:

“obtaining, documenting, and analyzing information potentially related to Gulf War illnesses; documenting the data and analysis in databases and other forms of storage; establishing a program to reach-out to veterans; developing questionnaires and surveys to collect data; developing maps and other multimedia presentations; plotting and analyzing troop movements and locations; rapidly creating data analysis tools to aid in analysis efforts; developing and producing case studies; preparing documents for storage on GulfLINK; developing recommendations and long range plans; writing papers; and, providing testimony.”

The task order also required BDM to provide facilities, furniture, telecommunications, equipment, and services, as needed.

Orders under multiple-award, task-or-delivery-order contracts are required by law to contain a statement of work that “clearly specifies all tasks to be performed or property to be delivered under the order.”¹³ In our opinion, this language means that a task order must identify with reasonable specificity the task or tasks that a contractor will be expected to perform, rather than merely list categories of services. The task order awarded to BDM, however, was basically a broad menu of services from which OSAGWI could pick and choose as the occasion arose and lacked the degree of specificity required. While we appreciate the exigent circumstances under which this award was made, we do not believe that the award of this broad task order was proper because it did not clearly specify the tasks to be performed. The DOD Inspector General also cited concerns with OSAGWI’s task orders to BDM.¹⁴

When OSAGWI reached its allotted cost ceiling under the NGB contract and the NGB did not increase the contract ceiling, OSAGWI continued the arrangement with BDM through an order under the General Services Administration’s Management, Organizational, Business Improvement Services (MOBIS) schedule contract. The MOBIS schedule states that it is intended to support business, management, and organizational improvement through activities such as quality management, benchmarking, reengineering, surveys, strategic planning, and development of leadership and management skills. The General Services

¹³10 U.S.C. § 2304c(c).

¹⁴See DOD Inspector General, *DOD Use of Multiple Award Task Order Contracts* – Report No. 99-116, Apr. 2, 1999.

Administration's summary of MOBIS services states that such contracts are not intended for independent management or technical studies.

The task order to BDM was outside the scope of the MOBIS contract. The work identified in the task order supports OSAGWI's operational functions and activities and does not fit properly within the scope of the contract. Specifically, the objective of the task order is to support OSAGWI's research and investigation into potential causes of Gulf War veterans' illnesses, rather than, as OSAGWI contends, to support efforts to improve managerial or organizational processes of the type intended for the MOBIS contract. In this regard, the MOBIS scope of work states that the "performance of operational activities" and database planning are not appropriate for purchase under MOBIS. Given the substantial disparity between the purposes of this contract and the BDM task order, we believe that the task order is outside the scope of the MOBIS contract and should not have been awarded under that contract. OSAGWI officials have informed us that this task order will expire in January 2000, but that the need for the type of support services that BDM is providing will continue for an indefinite period.

Competition for Task Order Discouraged

Under multiple award task order contracts, all of the multiple award contractors are to be given a fair opportunity to be considered for the award of any particular task order, typically by submitting proposals in response to agency announcements. Competition is one of the means by which agencies insure they obtain the best value from their contractors. OSAGWI's solicitation for one task order opportunity, however, discouraged competition among the multiple award contractors by naming Systems Research and Applications Corporation (SRA) as the preferred contractor.

We have testified and reported that naming preferred contractors in task order announcements discourages competition, frequently resulting in just one proposal being received.¹⁵ SRA was the only multiple award contractor that responded to the announcement.¹⁶ OSAGWI has not argued that SRA was uniquely qualified to perform the required work.

Conclusions

During fiscal years 1997-98, the government expended considerable funds on research and investigation into Gulf War veterans' illnesses—about \$121 million. More than half of this total was spent by the Office of the Special Assistant for Gulf War Illnesses.

Even though significant funding has been spent on research and investigation of Gulf War veterans' illnesses, most of the research is ongoing and the Research Working Group has not completed an assessment of the extent to which federal research objectives identified in 1995 have been satisfied. While about two-thirds of the 34 completed projects had resulted in peer-reviewed publications, researchers face increasingly difficult problems in identifying valid data on veterans' exposures. Moreover, little is known about how veterans' conditions have changed over time, no working case definitions have been endorsed in order to focus research efforts, and research on treatments has begun only recently. As a result, little knowledge exists concerning the causes, courses, or successful treatments for Gulf War veterans' illnesses. In addition, although the Office of the Special Assistant for Gulf War Illnesses has received most of the material requested of its research contractors, the review process established by the Office can be slow.

Coordination of planned efforts is key to maximizing the government's investment into research on Gulf War veterans' illnesses. However,

¹⁵*Defense Acquisition: Improved Program Outcomes Are Possible* (GAO/T-NSIAD-98-123, Mar. 18, 1998), and *Acquisition Reform: Multiple Award Contracting at Six Federal Organizations*, (GAO/NSIAD-98-215, Sept. 30, 1998). In response to our testimony, the Office of Management and Budget directed that the Federal Acquisition Regulation be revised to prohibit the naming of preferred contractors in task order announcements. The federal acquisitions regulation was revised to prohibit the designation of preferred awardees effective August 16, 1999.

¹⁶After the initial award was made to the preferred vendor identified in the announcement, succeeding awards were directed to the same vendor under an exception to the fair opportunity requirement for work that is a "logical follow-on" from prior work. Thus, the anticompetitive effect of directing the initial award was magnified in subsequent awards.

disagreement regarding which activities should be subject to coordination exists. As a result, the Office of the Special Assistant for Gulf War Illnesses, which spends more than half of the federal funds supporting research and investigation, has not effectively coordinated its activities with the Research Working Group.

DOD established the Office of the Special Assistant for Gulf War Illnesses to restore public confidence in DOD's efforts to deal with Gulf War illnesses issues. While officials of the Office of the Special Assistant for Gulf War Illnesses noted that they intended to seek advice on drawing down the office, they planned expenditures of \$65.4 million across fiscal years 1999 and 2000, and the Office remains in DOD's budget through fiscal year 2005. Because the Office spends a high percentage of its budget on support contracts, it is important that its contracting procedures comply fully with applicable laws and regulations.

Recommendations

With respect to the health research efforts coordinated by the Research Working Group of the Persian Gulf Veterans' Coordinating Board, we recommend that the Secretaries of Veterans' Affairs, Defense, and Health and Human Services direct the executive director of the Research Working Group to

- establish and achieve a target date within fiscal 2000 for publishing its assessment of progress toward addressing the research objectives it identified in 1995;
- compile data on the number of Gulf War veterans with unexplained illnesses, the progression of their illnesses, the treatments they are receiving, and the success of these treatments (recognizing that application of some working case definitions or categorization scheme may be useful for purposes of such an accounting); and
- effectively coordinate the efforts of the Office of the Special Assistant for Gulf War Illnesses with related activities of DOD, VA, and HHS to prevent duplication and improve the efficiency of resource use.

We also recommend that the Secretary of Defense direct the Office of the Special Assistant for Gulf War Illnesses to replace the task order issued under the MOBIS contract with a proper contracting arrangement as soon as practicable. In addition, the Secretary should direct the Office of the Special Assistant for Gulf War Illnesses that all future support contracts should comply fully with applicable laws and regulations.

Agency Comments and Our Evaluation

In written comments on a draft of our report, DOD and VA agreed with some of our findings and recommendations but disagreed with others, and CDC generally concurred with our findings and recommendations. DOD provided additional technical comments, which we incorporated as appropriate. Also, CDC requested that we incorporate additional information on two of its sponsored studies, which we did. (App. IV, V, and VI contain the written comments of DOD, VA, and CDC, respectively, and our evaluation of them.)

DOD commented that our report paints a pessimistic picture of the research on Gulf War veterans' health. The Department cited studies that compared the hospitalization in military facilities, the birth outcomes in military facilities, and the mortality of active duty Gulf War veterans to large groups of nondeployed veterans as support for a more optimistic perspective on veterans' health. However, DOD did not cite the most consistent finding of the health research to date; that is, Gulf War veterans seem to exhibit more of some symptoms, such as fatigue, difficulty concentrating, and muscle and joint pain, than do nondeployed veterans.¹⁷ DOD believes that the failure to identify a "unique syndrome" is an optimistic sign of veterans' health overall. We disagree. Even if the symptoms reported more often by Gulf War veterans are not confined to those veterans, DOD needs to explain why Gulf War veterans report these symptoms more frequently. Furthermore, none of the studies DOD cited examined the possible existence of significant differences in the health of Gulf War veterans based on specific exposures to hazardous materials during military service.¹⁸

¹⁷Institute of Medicine, *Gulf War Veterans: Measuring Health* (Washington, D.C.: National Academy Press, 1999), p. 2; Iowa Persian Gulf Study Group, "Self-Reported Illness and Health Status Among Gulf War Veterans: A Population-Based Study," *Journal of the American Medical Association*, 277 (3), (1997), pp. 238-245; and K. Fukuda, et al., "Chronic Multisymptom Illness Affecting Air Force Veterans of the Gulf War," *Journal of the American Medical Association*, 380 (11), (1998), pp. 981-88.

¹⁸One study argued that the Gulf War veterans may have been more fit than those not deployed; thus, the finding of no difference between the two groups might suggest a significant decline in the post-war health of the Gulf War veterans. R. Haley, "Point: Bias From the 'Health Warrior Effect' and Unequal Follow-up in Three Government Studies of Health Effects of the Gulf War," *American Journal of Epidemiology*, 148 (4), (1998), pp. 315-23.

DOD also said that we were incorrect in stating that little is known about how veterans' conditions have changed over time. However, our report is consistent with a September 1999 report of the Institute of Medicine. The report notes that there has been no systematic evaluation of whether or how veterans' health status is changing.¹⁹ Also, in a 1998 report to Congress, the Research Working Group stated that no government research is specifically directed toward understanding the progress of Gulf War veterans' illnesses over time and that research should determine the long-term health of these veterans.²⁰

DOD further stated that the effectiveness of government research has been demonstrated in a variety of ways. We agree that the research to date has added to what was known about Gulf War veterans' health shortly after the war. Nevertheless, little information is available on the extent or course of the development of veterans' undiagnosed illnesses, basic information on the prevalence of veterans' symptoms is unavailable, and no research on the treatment of such illnesses has been completed. Although joint commands have revised joint policy on record-keeping, and operational changes have been made to improve environmental monitoring, these changes do not serve as proof of research effectiveness. Rather, they address problems that have challenged Gulf War researchers in interpreting data on veterans' illnesses because they lack accurate and precise information (i.e., duration and doses) on veterans' exposures to hazardous materials.

Both DOD and VA concurred with our recommendation that the Research Working Group set a date in fiscal year 2000 for reporting its progress in addressing the research objectives it identified in 1995. DOD confirmed, as we noted in our draft report, that this report is in progress, but neither agency provided a specific date for its publication.

Regarding our recommendation that steps be completed to compile data on the number of Gulf War veterans with unexplained illnesses, the treatments they were receiving, and the success of these treatments, DOD partially concurred and VA did not concur. Neither agency opposed the collection of information on the number and health status of Gulf War veterans with

¹⁹ Institute of Medicine, *Gulf War Veterans: Measuring Health* (Washington, D.C.: National Academy Press, Sept. 1999), p. 3, 35.

²⁰ Persian Gulf Veterans' Coordinating Board – Research Working Group, *Annual Report to Congress – 1998* (Washington, D.C.: PGVCB RWG, June 1999), p. 53.

unexplained illnesses. However, VA stated that it could not implement the recommendation as worded without specific case definitions (that is, criteria to identify distinct illnesses). We agree that some categorization scheme or set of working case definitions would be useful in counting the numbers of veterans that have unexplained illnesses of some type, and we revised our recommendation accordingly.

Although DOD concurred with our recommendation that the Research Working Group coordinate with the Office of the Special Assistant for Gulf War Illnesses on activities related to Gulf War veterans' illnesses, DOD disagreed that its current coordination was weak. It stated that coordination was already occurring and that coordination on Office-sponsored reviews of scientific literature was unnecessary because the reviews were not research. VA did not concur with the recommendation because most of the work of the Office of the Special Assistant involves investigations of specific wartime incidents rather than research.

Regardless of whether the work of the Office is considered research or not, it describes the extent and nature of veterans' possible exposures to hazardous materials. These descriptions are important to researchers trying to identify the health consequences of such exposure. Moreover, the law does not limit the Working Group's coordination efforts to activities that constitute research, however defined. Accordingly, we are now recommending that the Research Work Group effectively coordinate the activities of the Office of the Special Assistant with related activities of DOD, VA, and the Department of Health and Human Services to prevent duplication of effort and optimize the use of resources. We are making this recommendation to prompt these organizations to work more closely on behalf of ill veterans. We believe that greater cooperation, exchange of information, and coordination will help expedite the process and help find solutions the veterans need.

Finally, DOD did not concur with our recommendation to replace an improperly awarded task order as soon as practicable and to comply fully with applicable laws and regulations in future contracting activities. DOD noted that because its Gulf War illnesses office does not have contracting officers, it relies on the professional judgment of contracting professionals outside that office, who did not object to the office's contract actions. DOD contends that the office complied with all legal requirements in effect at the time.

We note that DOD did not disagree with our conclusion that the task order was improperly awarded. The task order was for support of office operations in developing information related to Gulf War illnesses, even though the underlying contract prohibited its use for the performance of operational activities. The task order was therefore improper and should be terminated, if practicable, as we recommended.

We recognize that the Office of the Special Assistant relies on contracting professionals outside that office to execute its support contracts. Nevertheless, the office is, at a minimum, responsible for determining its requirements for support, a process that in one instance resulted in naming a preferred vendor and in another led to an overly broad statement of work. The effect of these practices is to discourage competition. It is important, therefore, that both requiring agencies, such as the Gulf War illnesses office, as well as agencies that execute contracts, adhere to the statutes and regulations designed to maximize competition.

Scope and Methodology

To determine how much DOD, HHS, and VA have spent on research and investigation of Gulf War veterans' illnesses and health concerns in fiscal years 1997 and 1998, we reviewed budget documents, contracts, and other relevant documents. We also interviewed RWG members, as well as DOD, HHS, and VA officials managing the respective agencies' budgeting for research, investigation, and clinical care. During our interviews, we inquired about spending levels and the distribution of funds across activities.

The expenditure estimates included in this report are limited to DOD, VA, and HHS. Because we targeted key entities within these agencies on the basis of the public profile of their research and investigatory efforts, the expenditures we identified may exclude related spending by entities that have not been prominently identified with the federal effort. We did not independently assess the estimates provided us by the various agencies and offices apart from determining that they were basically consistent with the contract documents examined.

To determine the status of research efforts and identify research products, we reviewed research and investigatory objectives, reports to Congress, agency documents, and articles appearing in peer-reviewed journals. In addition, we interviewed researchers, PGVCB officials, and officials at the sponsoring agencies. We did not independently assess the appropriateness

of federal research objectives, nor did we determine how well federally sponsored research had addressed them.

To investigate the extent of coordination between OSAGWI and the RWG, we interviewed members of OSAGWI; the RWG; representatives from DOD, HHS, and VA; and researchers about the process. We reviewed agency documents and the minutes of PGVCB and other meetings and examined research protocols, contracts, and documentation of reviews conducted by sponsoring agencies into research and investigatory activities.

To determine the expenditures and resources OSAGWI had directed toward veterans' health concerns and the way it managed its contracts, we interviewed OSAGWI officials and contracting officers and reviewed contracts, task orders, statements of work, copies of deliverables, and requested any assessments of contractor performance. For efficiency, we limited the review to four support and five research contracts, which accounted for 91 percent and 72 percent of OSAGWI's expenditures in the respective areas.

Our work was conducted from May 1998 through December 1999 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies of this report to other interested congressional committees and members.

If you have any questions or would like additional information, please contact those listed in appendix VII.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Kwai-Cheung Chan', with a stylized flourish at the end.

Kwai-Cheung Chan
Director, Special Studies and Evaluations

Research Objectives Identified by the Research Working Group of the Persian Gulf Veterans' Coordinating Board

1. What is the prevalence of symptoms/illnesses in the Persian Gulf veteran population? How does this prevalence compare to that in an appropriate control group?
2. What was the overall exposure risk of troops to *Leishmania tropica*?
3. What were the exposure concentrations to various petroleum products, and their combustion products, in typical usage during the Persian Gulf conflict?
4. What was the extent of exposure to specific occupational/environmental hazards known to be common in the Persian Gulf veteran's experience? Was this exposure different from that of an appropriate control group?
5. What were the potential exposures of troops to organophosphate nerve agent and/or sulfur mustard as a result of allied bombing at Muhammadiyah and Al Muthanna, or the demolition of a weapons bunker at Khamisiyah?
6. What was the extent of exposure to chemical agent, other than at Khamisiyah, Iraq, in the Persian Gulf as a function of space and time?
7. What was the prevalence of PB use among Persian Gulf troops?
8. What was the prevalence of various psychophysiological stressors among Persian Gulf veterans? Is the prevalence different from that of an appropriate comparison population?
9. Are Persian Gulf veterans more likely than an appropriate comparison group to experience non-specific symptoms and symptom complexes?
10. Do Persian Gulf veterans have a greater prevalence of altered immune function or host defense when compared with an appropriate control group?
11. Is there a greater prevalence of birth defects in the offspring of Persian Gulf veterans than in an appropriate control population?
12. Have Persian Gulf veterans experienced lower reproductive success than an appropriate control population?
13. Is the prevalence of sexual dysfunction greater among Persian Gulf veterans than among an appropriate comparison population?

**Appendix I
Research Objectives Identified by the
Research Working Group of the Persian Gulf
Veterans' Coordinating Board**

14. Do Persian Gulf veterans report more pulmonary symptoms or diagnoses than persons in appropriate control populations?
15. Do Persian Gulf veterans have a smaller baseline lung function in comparison to an appropriate control group? Do Persian Gulf veterans have a greater degree of non-specific airway reactivity in comparison to an appropriate control group?
16. Is there a greater prevalence of organic neuropsychological and neurological deficits in Persian Gulf veterans compared to appropriate control populations?
17. Can short-term, low-level exposures to pyridostigmine bromide, the insect repellent DEET, and the insecticide permethrin, alone or in combination, cause short-term and/or long-term neurological effects?
18. Do Persian Gulf veterans have a significantly higher prevalence of psychological symptoms and/or diagnoses than do members of an appropriate control group?
19. What is the prevalence of leishmaniasis or other infectious diseases in the Persian Gulf veteran population?
20. Do Persian Gulf veterans have a greater risk of developing cancers of any type when compared with an appropriate control population?
21. Are Persian Gulf veterans experiencing a mortality rate that is greater than that of an appropriate control population? Are specific causes of death related to service in the Persian Gulf?

Reports Received and Released by the Office of the Special Assistant Under Research Contracts Examined by GAO

Contractor	Contract amount	Topics/titles	Due	Received	Form and date of earliest known receipt	Released (as of 12/15/99)
Mitre Corporation ^a	\$3,185,000	Iraqi Chemical Warfare Study	Yes	Yes	Classified draft report (4/4/97) ^b	Partial (9/5/97) ^c
RAND	\$3,200,000	Oil Fires: A Review of the Scientific Literature as It Pertains to Illnesses of Gulf War Veterans	Yes ^d	Yes	Partial draft (12/97). Draft for agency review (4/16/98).	Yes ^e (11/5/98)
		A Review of Scientific Literature as It Pertains to Gulf War Illnesses, Volume V: Depleted Uranium	Yes ^d	Yes	Draft for agency review (8/4/98).	Yes (4/16/99)
		A Review of the Scientific Literature as It Pertains to Gulf War Illnesses, Volume VI: Chemical and Biological Warfare Agents	Yes ^d	Yes	Draft for agency review (9/1/98).	No
		A Review of the Scientific Literature as It Pertains to Gulf War Illnesses: Volume III: Pyridostigmine Bromide	Yes ^d	Yes	Draft for agency review (6/10/98).	Yes (10/19/99)
		Stress: A Review of the Scientific Literature as It Pertains to Health Problems of Gulf War Veterans	Yes ^d	Yes	Draft for agency review (4/23/98).	Yes (5/19/99)
		Infectious Disease	Yes ^d	Yes ^f	Draft for agency review (2/11/98).	No
		Immunizations	Yes ^d	Yes	Draft for agency review (4/22/99).	No
		Military Uses of Drugs Not Yet Approved by FDA for BW/CW Defense: Lessons from the Gulf War	Yes ^d	Yes	Draft for agency review (4/24/98).	Yes (4/16/99)
		Assessing the Health Effects of Military Deployments: DOD's Activities Following the Gulf War	Yes ^d	Yes	Draft for agency review (9/15/98).	No
		Notes on the history of stress	Yes ^d	No	Not received as of 12/20/99.	No
Pesticides	Yes ^d	Yes	Draft for agency review (11/3/98).	No		
Institute for Defense Analyses	\$389,000	Full Dimensional Protection: Military Records and Reports Dimension	Yes	Yes	Draft for agency review (12/10/97) Revised draft (7/28/98).	No ^f

(Continued)

**Appendix II
Reports Received and Released by the Office
of the Special Assistant Under Research
Contracts Examined by GAO**

Contractor	Contract amount	Topics/titles	Due	Received	Form and date of earliest known receipt	Released (as of 12/15/99)
		Safe and Timely Disposal in Wartime of Large Quantities of Captured Chemical and Biological Munitions	Yes	Yes	Draft for agency review (11/8/97).	No ^g
		Protecting Against the Uncertain Risks of Exposure to Very Low Concentrations of Chemical Warfare Nerve Agents	Yes	Yes	Draft received 9/99.	No
		[A paper describing planned and possible alternative approaches for improving DOD capabilities to detect chemical agents on the battlefield and archive such data]	Yes	Yes	Report delivered 6/16/97.	No
National Academy of Sciences	\$2,703,809 ^h	Force Protection: Lessons Learned from the Gulf War	No ⁱ	No ⁱ	No final report due before 3/31/00.	
Birch & Davis Associates	\$176,500 ^k	Birth Defects Among Children of Gulf War Veterans and Potential Nerve Agent Exposure	Yes	Yes	Draft for agency review (8/21/98).	No ^l
		Comprehensive Clinical Evaluation Program Gulf War Studies and Analyses: Report on Findings from a Telephone Survey of Persian Gulf War Veterans Assigned to Demolition Units	Yes	Yes	Draft for agency review (12/1/97).	No
		Toxicity Assessment and Risk Evaluation for Exposure of U.S. Troops to Chemical Agents at Khamisiyah	Yes	Yes	Draft for agency review (5/22/98).	No
		Admissions to Field Hospitals During the Gulf War and Potential Nerve Agent Exposures	Yes	Yes	Draft for agency review (7/16/98).	No
Total	\$9,654,309		20	19		6

(Continued from Previous Page)

Appendix II
Reports Received and Released by the Office
of the Special Assistant Under Research
Contracts Examined by GAO

^aMitre contracted with the Assistant to the Secretary of Defense for Intelligence Oversight, but the Office of the Special Assistant for Gulf War Illnesses (OSAGWI) was directed to provide \$3,185,000 to support Mitre's work on the study. Although OSAGWI does not have direct oversight of the effort, the status of the study is shown here in the interest of tracking the products associated with funds provided to OSAGWI.

^bThe Office of the Assistant Secretary of Defense for Intelligence Oversight reported that no final report was available as of July 27, 1998.

^cA declassified version of chapter 11 of this report was released by OSAGWI on September 5, 1997, in response to a request from the Presidential Advisory Committee on Gulf War Veterans' Illnesses. An official of the Office of the Assistant Secretary of Defense for Intelligence Oversight indicated on December 15, 1999 that he expected the report to be transmitted to the Secretary on or before December 25, 1999 accompanied by a recommendation for release of a substantial portion in unclassified form.

^dProducts of the RAND contract were originally due in September 1997. A December 1997 modification to RAND's agreement with the Department of Defense (DOD) reestablished due dates between December 1997 and January 1998.

^eIn many instances, the deadlines on these products were extended or the Office was slow to provide the official comment necessary for the contractor to issue a final product. OSAGWI also instituted a review process that incorporated comments from various government agencies. This process has required months to apply, and some deliverables spent a year or longer in unreleased or draft form. OSAGWI officials indicated that they initiated the external review process at the urging of the Research Working Group (RWG), but Group officials said that they encouraged an external, university-based review process, not the extensive interagency review OSAGWI adopted.

^fOSAGWI officials told us that this document was finalized in August 1999 and distributed to the Office of the Secretary in October 1999, but has not been publicly released.

^gOSAGWI officials told us that this document was finalized in October 1999 and distributed to the Office of the Secretary in November 1999, but has not been publicly released.

^hThe total cost of this contract over the anticipated period of performance, including option years, is expected to be \$5,922,305.

ⁱNone of the report deliverables for this contract, apart from progress and status reports, was due before March 29, 1999, when a draft panel report was expected. A final interim report is due on March 29, 2000, and a final consensus report on September 29, 2000.

^jSubsidiary products from this contract have been provided and released. [The National Academy Press has released the following documents in 1999 as part of a series on Strategies to Protect the Health of Deployed U.S. Forces: \(1\) *Medical Surveillance, Record Keeping and Risk Reduction*; \(2\) *Analytical Framework for Assessing Risks \(and Workshop Proceedings: Strategies to Protect the Health of Deployed U.S. Forces: Assessing Health Risks to Deployed U.S. Forces\)*; and \(3\) *Strategies to Protect Deployed U.S. Forces: Force Protection and Contamination*.](#)

^kThe total amount of funds OSAGWI reported as supporting its research contract with Birch & Davis in fiscal years 1997 and 1998. The total cost of delivery order 46 for contract number DASW01-95-D-0026 was \$1,684,773, but this order also covered substantial work for DOD/Health Affairs and its Deployment Surveillance Team to validate and analyze data from the Comprehensive Clinical Evaluation Program and other surveillance activities. Cost information is not available by product.

^lAn April 9, 1997, request by Birch & Davis Associates for approval to disseminate and/or publish articles based on analyses conducted under delivery order 46 was formally rescinded by an April 15, 1997, letter that cited a conversation on the subject that led the contractor to understand "that any request to disseminate and/or publish articles under the referenced contract must be done on a 'case by case' basis and must be accompanied by a definite publication plan." In explanation of non-release of one or more of this contractor's products, OSAGWI staff cited dissatisfaction with the deliverables as presented by the contractor in July 1998. However, they provided no written performance reviews for the contractor, explaining that the products were developed under a task order that was part of a contract with the Office of the Assistant Secretary of Defense for Health Affairs, which was presumably responsible for evaluating the contractor's performance.

Sample Working Case Definitions Describing Symptoms Experienced by Gulf War Veterans

Origin	Date	Inclusion criteria	Exclusion criteria
Sanford ^a	1994	(1) In theater of operations between 8/8/90 and late July 1991 (2) New onset of a symptom complex with the occurrence of at least five of eight minor criteria: fatigue, arthralgia, headache, diarrhea, neuropsychiatric complaints, difficulty sleeping, low-grade fever, and/or weight loss.	Other clinical conditions with similar symptomologies based on thorough evaluation, including history, physical exam and appropriate lab studies.
Haley ^b	1997	The three primary syndromes are impaired cognition (symptoms include distractibility, difficulty remembering, depression, middle and terminal insomnia, fatigue, slurring of speech, confused thought process, and migraine-like headaches); confusion-ataxia (symptoms include problems with thinking and reasoning processes, getting confused, getting disoriented, problems keeping their balance, posttraumatic stress disorder, depression, liver disease, and sexual impotence); and arthro-myo-neuropathy (symptoms include generalized joint and muscle pains, increased difficulty lifting heavy objects, muscle exhaustion after exertion, and tingling or numbness of the hands, arms, feet, and legs).	
CDC ^c	1998	One or more chronic symptoms (present for more than 6 months) from at least two of the following three categories: fatigue, mood and cognition (feeling depressed, difficulty remembering or concentrating, feeling moody, feeling anxious, trouble finding words or difficulty sleeping), and/or musculoskeletal (joint pain, stiffness, or muscle pain).	Other clinical conditions with similar symptomologies based on thorough evaluation, including history, physical exam and appropriate lab studies.
National Health Survey Team ^d	1999	Combination of blurred vision, loss of balance/dizziness, tremors/shaking, and speech difficulty (reported by 277, or 2.4 percent, of surveyed Gulf-deployed veterans in contrast to 43 or 0.5 percent of surveyed nondeployed veterans).	

^aMemorandum from Jay P. Sanford, M.D. to MG Ronald Blanck, MC USA, re: Gulf War Syndrome: Proposed Provisional Case Definition, Jan. 27, 1994.

^bRobert W. Haley et al., "Is There a Gulf War Syndrome? Searching for Syndromes by Factor Analysis of Symptoms," *Journal of the American Medical Association*, vol. 277 (Jan. 15, 1997), pp. 215-222.

^cKeiji Fukuda et al., "Chronic Multisymptom Illness Affecting Air Force Veterans of the Gulf War," *Journal of the American Medical Association*, vol. 280 (Sep. 16, 1998), pp. 981-988.

^dNational Health Survey Research Team, "Unique Cluster of Symptoms Among Gulf Veterans," In The Research Working Group [of the] Persian Gulf Veterans Coordinating Board, *Conference on Federally Sponsored Gulf War Veterans' Illnesses Research: Program and Abstract Book*, 1999, p. 99.

Comments From the Department of Defense

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 19 1999

Mr. Kwai-Cheung Chan
Director, Special Studies and Evaluations
National Security and International Affairs Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Chan:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report, "GULF WAR ILLNESSES: Management Actions Needed to Answer Basic Research Questions", dated July 16, 1999 (GAO Code 713038/OSD Case 1865).

Federal Gulf War veterans' illnesses research encompasses a wide variety of research approaches (basic research through applied research) spanning a broad spectrum of technical disciplines. The effectiveness of this research has been demonstrated through the refinement of future research direction, progress in the development of clinical treatment efforts, changes in health care operations policy and doctrine to emphasize military force health protection, publications in the technical literature, and the outcomes of peer review. Still, the full impact of Federal Gulf War veterans' illnesses research will not be realized for years.

The GAO paints a pessimistic picture and incorrectly states that "little is known about how veterans conditions have changed over time." Although further research is in progress, a more optimistic perspective on veterans' health has been provided by an extensive descriptive and analytic epidemiological research effort based on clinical evaluations and medical records. Systematic clinical examinations have not identified a unique syndrome or a characteristic organic abnormality among over 100,000 U.S., British, and Canadian Gulf War veterans. Additionally, the mortality rate of Gulf War veterans has been less than half that of the civilian population, and overall deaths due to medical causes have not increased. Moreover, there has been no overall increase in hospitalizations among Gulf war veterans or birth defects among their children.

Significantly, the GAO fails to understand that the Office of the Special Assistant for Gulf War Illnesses (OSAGWI) is not responsible for either DoD's medical programs or medical research. OSAGWI's unique charge is to investigate and explain what occurred. OSAGWI's sponsorship of the RAND

See comment 1.
See comment 2.

See comment 3.

See comment 4.

See comment 5.

See comment 6.

See comment 7.

See comment 8.

See comment 9.



Appendix IV
Comments From the Department of Defense

See comment 9.

literature reviews was meant to inform, not to conduct research. Since the literature reviews are not research, they do not fall under the Research Working Group (RWG). Consequently, DoD disagrees with GAO's assertion that coordination between the RWG and OSAGWI is weak. The Draft Report does not state exactly what "weak coordination" means, and also does not mention that an OSAGWI representative is a formal member of the RWG and provides input.

See comment 10.

DoD agrees with the GAO recommendation that the RWG should publish a more formal assessment of progress toward addressing the research objectives identified in 1995. However, the GAO omits that this update is a work in progress and was ongoing at the time of the GAO audit. The GAO also fails to note the extensive research management, ongoing assessment, and oversight provided by the RWG since identifying research objectives in 1995. It is important to note that the annual reports published by the RWG analyze the Federal Government's portfolio of research on Gulf War veterans' illnesses, highlighting significant research and research-related events and milestones, discussing the management of federal Gulf War veterans' illnesses research programs (including research oversight, peer-review and coordination), and articulating priorities for future research. The GAO also omits the DoD-specific review of the research program by the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee and by an independent panel of experts during the Technology Area Review and Assessment (TARA). Both these forums have provided oversight and guidance to the DoD biomedical research efforts to date on illnesses among Gulf War veterans. Program management, oversight, and assessment is continuous.

See comment 11.

The GAO apparently did not consider ongoing work by the Departments of Defense, Veterans Affairs, and Health and Human Services when making the recommendation to "ensure that steps are completed to compile data on the number of veterans with Gulf War Illnesses, the progression of their illnesses, the treatments they are receiving, and the success of their treatments." Gulf War veterans have experienced a wide variety of diagnosed and undiagnosed medical conditions, which span the entire range of medical experience. DoD reiterates the consensus of the scientific community, including prior findings of the Institute of Medicine, that Gulf War veterans' illnesses appear to be a heterogeneous group of disorders, exhibiting widely varying manifestations and not amenable to a single unifying case definition. Therapeutic approaches have been tailored appropriately to each individual veteran's needs. However, the methodology for evaluating health outcomes and treatment efficacy in such a complex situation has not been developed. The task of designing a protocol for acquiring and analyzing longitudinal information to provide an accurate assessment of the health outcomes and treatment results in Gulf War veterans poses a significant challenge. Consequently, last year the Departments of Defense and Veterans Affairs requested that the National Academy of Sciences establish a committee to consider these methodological questions. The final report from the Academy is expected later this month.

Appendix IV
Comments From the Department of Defense

See comment 12.

DoD also disagrees with GAO's criticism of OSAGWI's contracting practices. OSAGWI does not have its own independent contracting officers, but relies upon the professional judgment of government contracting professionals. Contracting officers at GSA FEDSIM, National Guard Bureau, Defense Supply Service – Washington, GSA Kansas City and the National Institute of Health agreed with various OSAGWI contract actions, and raised no objections to them.

Lastly, DoD strongly objects to the wording of Recommendation 3 because it implies that OSAGWI did not obey the law when contracting. As previously stated, federal contracting personnel reviewed the BDM and SRA task orders and raised no objections. OSAGWI's contracts complied with all applicable laws and regulations.

DoD's summary and detailed comments on the Draft Report are set forth in the enclosures.

Sincerely yours,



Bernard Rostker

Enclosures

“GULF WAR ILLNESSES: Management Actions
Needed to Answer Basic Research Questions,”
Dated July 16, 1999
(GAO Code 713038/OSC Case 1865)

DEPARTMENT OF DEFENSE COMMENTS
TO THE GAO RECOMMENDATIONS

RECOMMENDATION 1: The GAO recommended that the Secretaries of Veterans’ Affairs, Defense, and Health and Human Services direct the Executive Director of the Persian Gulf Veterans Coordinating Board’s Research Working Group (RWG) to ensure that:

- The RWG establishes a date within fiscal 1999 or 2000 for publishing its assessment of progress toward addressing the research objectives it identified in 1995;
- Steps are completed to compile data on the number of veterans with Gulf War illnesses, the progression of their illnesses, the treatments they are receiving, and the success of these treatments;
- The RWG defines research activities and takes necessary steps to ensure any efforts meeting this definition by the Office of the Special Assistant for Gulf War Illnesses (OSAGWI) are subject to coordination. (pp. 16-17/GAO Draft Report)

DOD RESPONSE:

Part 1, Concur: DoD agrees that the RWG publish a more formal assessment of progress towards addressing the research objectives identified in 1995. In fact, this update is a work in progress and was ongoing at the time of the GAO audit. The Department has also performed extensive research management, ongoing assessment, and oversight through the RWG since identifying research objectives in 1995. The annual reports published by the RWG analyze the Federal Government’s portfolio of research on Gulf War veterans’ illnesses, highlighting significant research and research-related events and milestones, discussing the management of federal Gulf War veterans’ illnesses research programs (including research oversight, peer-review and coordination), and articulating priorities for future research.

See comment 10.

Part 2, Partially Concur: While the Department is pursuing the compilation of data, this task is not as basic as the Draft Report implies. The Departments of Defense, Veterans Affairs, and Health and Human Services are currently working together to “ensure that steps are completed to compile data on the number of veterans with Gulf War Illnesses, the progression of their illnesses, the treatments they are receiving, and the success of their treatments.” However, Gulf War veterans have experienced a wide variety of diagnosed and undiagnosed medical conditions, which span the entire range of medical experience. DoD concurs with the consensus of the scientific community, including prior findings of the Institute of Medicine, that Gulf War veterans’ illnesses appear to be a heterogeneous group of disorders, exhibiting widely varying manifestations and not amenable to a single unifying case definition.

See comment 11.

Appendix IV
Comments From the Department of Defense

See comment 11.

Therapeutic approaches have been tailored appropriately to each individual veteran's needs. To date, the methodology for evaluating health outcomes and treatment efficacy in such a complex situation has not been developed. Consequently, the task of designing a protocol for acquiring and analyzing longitudinal information to provide an accurate assessment of the health outcomes and treatment results in Gulf War veterans poses a significant challenge. Consequently, last year the Departments of Defense and Veterans Affairs requested that the National Academy of Sciences establish a committee to consider these methodological questions. The final report from the Academy is expected later this month.

See comment 9.

Part 3, Concur: While the Department agrees that there should be a close coordination between the two entities on research activities, we believe this is already occurring. It appears that the GAO has misinterpreted OSAGWI's mission, since OSAGWI is not responsible for either DoD's medical programs or medical research. OSAGWI's unique charge is to investigate and explain what occurred. Therefore, OSAGWI's sponsorship of the RAND literature reviews was meant to inform, not to conduct research. Since the literature reviews are not research, they do not fall under the RWG. Consequently, DoD disagrees with GAO's assertion that coordination between the RWG and OSAGWI is weak. The Draft Report does not state exactly what "weak coordination" means, and also does not mention that OSAGWI is a formal active member of the RWG.

RECOMMENDATION 2: The GAO also recommended that the Secretary of Defense direct the OSAGWI to replace the task order issued under the General Service Administration's Management, Organizational, Business Improvement Services (MOBIS) schedule contract with a proper contracting arrangement as soon as it is practical to do so. (P.17/GAO Draft Report)

DOD RESPONSE:

Not Concur: DoD disagrees with GAO's criticism of OSAGWI's contracting practices. OSAGWI does not have its own independent contracting officers, but relies upon the professional judgment of government contracting professionals. Contracting officers at GSA FEDSIM, National Guard Bureau, Defense Supply Service – Washington, GSA Kansas City and the National Institute of Health agreed with various OSAGWI contract actions, and raised no objections to them.

See comment 12.

RECOMMENDATION 3: The GAO further recommended that the Secretary of Defense direct OSAGWI to ensure that all future support contracts comply fully with applicable laws and regulations. (p. 17/GAO Draft Report).

DOD RESPONSE

Not Concur: DoD strongly disagrees with the wording of this recommendation because it implies that OSAGWI did not obey the law when contracting. OSAGWI's contracting actions complied with the laws and regulations in effect at the time of award. Moreover, numerous federal contracting officials reviewed OSAGWI's various task orders and did not raise any objections.

GAO Comments

The following is GAO's response to the Department of Defense's (DOD) comments dated August 19, 1999.

1. With respect to the refinement of future research direction, it is important to note that a National Institutes of Health working group assembled in 1994 noted the desirability of identifying one or more case definitions or an evolving case definition to focus research efforts. Our report notes that the Research Working Group had not endorsed one or more case definitions that might focus future research efforts on veterans' unexplained illnesses and that problems with exposure data persist.
2. Our report notes that 8 years after the war, the Department of Veterans' Affairs has just begun to recruit subjects for clinical trials and no treatment research has yet been completed. We have not evaluated the quality of these trials or the selection of treatments to be evaluated.
3. Longitudinal follow-up of mortality, cancer rates, and health status will require many years. However, without accurate and precise exposure data (i.e., duration and dose), the interpretation of morbidity and mortality data from these studies will remain challenging.

4. The facts and observations in this report are consistent with those of the Institute of Medicine (IOM). The Institute noted in a report issued in mid-September 1999, the month after DOD provided its formal comments, that no one has systematically evaluated whether the health of Gulf War veterans is changing and, if so, how. Similarly, it noted that no one had determined the number of veterans who have symptoms of illnesses that they attribute to service in the Gulf War, or whether the health of these veterans is better than, worse than, or the same as that of veterans who were not deployed to the Gulf War, although some studies have found higher levels of reported symptoms among Gulf War veterans.¹ In addition, RWG, in its annual report to Congress for 1998 stated that, “although several individual research projects...have longitudinal components built into them, no research is specifically directed toward understanding the progress of Gulf War veterans’ illnesses over time. The RWG has concluded that to the extent feasible, research approaches need to be applied to determine the long-term health of Gulf War veterans in contrast to the several cross-sectional epidemiological research projects recently completed or still ongoing.”²

¹Institute of Medicine, *Gulf War Veterans: Measuring Health*.

²Persian Gulf Veterans’ Coordinating Board – Research Working Group, *Annual Report to Congress – 1998*.

5. It has been difficult for researchers to progress from descriptive to analytical epidemiology due partly to the absence of accurate and precise data on the factors to which veterans were exposed. None of the research DOD cited compared veterans on the basis of their specific exposure history. Instead, results generally describe the experience of persons who were on active duty in the Gulf War theater (that is, the Persian Gulf, Kuwait, Iraq, Saudi Arabia, the Red Sea, the Gulf of Oman, the Gulf of Aden, the northern portion of the Arabian Sea, Oman, Bahrain, Qatar, or the United Arab Emirates) between August 2, 1990, and June 13, 1991, as compared to those who were on active duty elsewhere during this time frame. As we noted in 1997, one might not find differences between these large and diverse groups even if some veterans have illnesses that are significantly related to specific military exposures. Nonetheless, researchers have documented that these two groups differ in their frequency of reporting various symptoms and, even with poorly defined exposures, some investigators have reported associations between certain exposures and indicators of veterans' post-war health.³

³See, for example, S. P. Proctor et al., "Health Status of Persian Gulf War Veterans: Self-reported Symptoms, Environmental Exposures, and the Effect of Stress," *International Journal of Epidemiology*, 27 (6), 1000-10. Unwin, C. et al. (1999.) Health of U.K. Servicemen Who Served in Persian Gulf War. *Lancet*, 353, 169-178. Haley, R. W., & Kurt, T. L. (1997). Is There a Gulf War Syndrome? *Journal of the American Medical Association*, 277 (3), 215-22 and related articles at 223-37.

6. DOD's comments do not embrace the most consistent finding of the health research to date. As IOM concluded, "There does seem to be a higher prevalence of some symptoms among veterans who served in the Gulf War as compared to nondeployed veterans. The primary symptoms include fatigue, difficulty concentrating, memory loss, skin rash, headache, and muscle and joint pain."⁴ Several studies support this conclusion. For example, a study funded by the Centers for Disease Control conducted telephone interviews of a stratified random sample of 3,695 of 29,000 Gulf War-era military personnel listing Iowa as their home of record and found that those deployed to the Gulf War were more likely than those who served elsewhere during the war to report symptoms suggestive of cognitive dysfunction, depression, chronic fatigue, post-traumatic stress disorder, and respiratory illness (asthma and bronchitis).⁵ These symptoms appeared to affect the functional activity and daily lives of the Gulf War veterans. Similarly, a CDC study of Air Force personnel found that a multisymptom case definition developed after clinical examination of 158 veterans was, in its severe form, reported several times more frequently by sampled Gulf War veterans than by nondeployed personnel.⁶ Mild-to-moderate cases, while more evenly spread, were still well over twice as common in the Gulf War group. Gulf War veterans classified as having mild-to-moderate and severe illness had a significant decrease in functioning and well-being compared with Gulf War veterans who did not fit the criteria for the multisymptom illness. Similar findings were reported in a study of 3000 veterans from New England, a study of 525 women veterans, and a study of 8,000 veterans from the United Kingdom.⁷ Moreover, a survey of Canadian veterans found significantly higher rates of self-reported chronic conditions and symptoms of a variety of conditions among Gulf-deployed veterans compared to those serving elsewhere during the Gulf conflict.⁸ The conditions reported more frequently by Gulf War

⁴Institute of Medicine (1999). *Gulf War Veterans: Measuring Health*, Washington, D.C.: National Academy Press, p. 2.

⁵Iowa Persian Gulf Study Group. (1997). Self-reported Illness and Health Status Among Gulf War Veterans: A Population-Based Study. *Journal of the American Medical Association*, 277 (3), 238-245.

⁶See Fukuda, K. et al. (1998.) Chronic Multisymptom Illness Affecting Air Force Veterans of the Gulf War. *Journal of the American Medical Association*, 280, 981-88. They report that 6.0% of 1155 Gulf War veterans they surveyed reported symptoms that fit their working definition of a severe case of multisymptom illness, while only 0.7% of the 2520 surveyed non-deployed personnel did so. The investigators reported that the univariate association between Gulf War veteran status and fitting the severe case criteria was statistically significant (odds ratio =12.7 with 95% confidence limits between 7.5 and 21.5).

veterans included problems with bones and joints, allergies, and limitations in activity due to health.

It is common throughout the epidemiological literature to accept a statistically significant difference in the risk of an illness as evidence of association. Even if the symptoms disproportionately reported by Gulf War veterans are not confined to these veterans, their increased frequency among Gulf War veterans needs to be explained. IOM has similarly concluded that, "It appears that veterans who served in the Gulf are more likely than their nondeployed comrades or civilians to experience a set of symptoms that include cognitive, musculoskeletal and energy/fatigue elements. In some cases, the symptoms are severe enough to be totally debilitating. Not all veterans experience the same cluster of symptoms; therefore, assuming a single underlying pathology or single cause for the complaints would not be appropriate."⁹

⁷Wolfe, J. et al. (1998.) Health Symptoms Reported by Persian Gulf War Veterans Two Years After Return. *American Journal of Industrial Medicine*, 33, 104-113. Unwin, C. et al. (1999.) Health of U.K. Servicemen Who Served in Persian Gulf War. *Lancet*, 353, 169-178. Pierce, P. (1997.) Physical and Emotional Health of Gulf War Veteran Women. *Aviation, Space and Environmental Medicine*, 68, 317-21.

⁸Goss Gilroy, Inc. (1998.) *Health Study of Canadian Forces Personnel Involved in the 1991 Conflict in the Persian Gulf*, vol. 1. Ottawa: Goss Gilroy.

⁹Institute of Medicine (1999). *Gulf War Veterans: Measuring Health*, Washington, D.C.: National Academy Press, p. 33.

7. Veterans of the Gulf War differ from the general civilian population with respect to fitness profile and other factors, so it is not surprising that their mortality rate would also differ from the rate for the general civilian population. Research found the mortality rate of Gulf War veterans through September 1993 to be slightly higher than that of veterans of the same era who served elsewhere, with the difference explained largely by greater mortality in motor vehicle accidents.¹⁰ In the published report of the mortality study, the authors speculate that increased mortality in automobile accidents might be attributed to increased risk-taking among war veterans in general, but they note that the reasons for the excess of deaths due to external causes among war veterans are not well understood. The finding was replicated in a follow-up study extending the observation period through December 1997.¹¹

¹⁰The odds ratio for this difference was 1.09 with 95% confidence limits between 1.01 and 1.16. See Kang, H.K. & Bullman, T. A. (1996.) Mortality Among U.S. Veterans of the Gulf War. *New England Journal of Medicine*, 335, 1498-1504. See also Haley, R. W., (1998.) "Commentaries: Point: Bias from the 'Healthy Warrior Effect' and Unequal Follow-up in Three Government Studies of Health Effects of the Gulf War." *American Journal of Epidemiology*, 148 (4), pp. 315-338.

¹¹The follow-up study found that the excess in deaths attributable to motor vehicle accidents persisted among Gulf War veterans observed through December 1997 (crude rate ratio = 1.32; confidence interval 1.23-1.41), while the risk of disease related deaths did not increase or decrease over time. See Kang, H.A. & Bullman, T. A. (1999). Mortality Among U.S. Veterans of the Gulf War: Update Through December 1997. *Conference on Federally Sponsored Gulf War Veterans' Illnesses Research: Program and Abstract Book*, (June 23-25, 1999). Washington, D.C.: The Research Working Group of the Persian Gulf Veterans' Coordinating Board, p. 28.

8. DOD does not note the methodological limitations of these studies as their authors do in the respective published reports. As noted by IOM, the studies of hospitalization (Gray et al., 1996; Knoke and Gray, 1998) and adverse birth outcomes (Araneta et al., 1997; Cowen et al., 1997) have been limited to personnel remaining on active duty and to events occurring in military hospitals. Conceivably, those suffering from Gulf War-related symptoms might leave active duty voluntarily or take a medical discharge. Hospitalizations for that group would appear in VA or private sector databases but not in the DOD database. The health or characteristics of active duty personnel could differ from those of personnel who have left active duty or who have been treated in nonmilitary hospitals. Moreover, economic and other non-health-related factors are likely to affect use of nonmilitary hospitals and health care services.¹² However, through 1993, studies did not observe an increase in hospitalization among deployed versus nondeployed veterans in the active duty military. Knoke and Gray, analyzing the same database, observed slightly more admissions for symptoms, signs and ill-defined conditions among Gulf-deployed veterans than among veterans deployed elsewhere during the same timeframe. They attributed the difference to admissions for evaluation purposes under the Comprehensive Clinical Evaluation Program, which offered examination and diagnostic services to Gulf War veterans.

9. Whether OSAGWI performs medical research is not relevant to determining whether the Research Working Group should coordinate its activities. We see nothing in the law that would limit the Group's coordinating efforts to activities that constitute research, however defined.

DOD also contends that OSAGWI does not need to coordinate with RWG and that it has coordination mechanisms. However, DOD's assertion that close coordination is already occurring is difficult to reconcile with our finding that duplication has occurred. Federal agencies have commissioned at least three reviews of the health effects of depleted uranium in the last few years, one each by the agencies represented on RWG. In addition, two major efforts to review the health effects of Gulf War veterans' exposures have been pursued more or less independently – one by RAND, under contract to DOD, and another by the National Academy of Sciences, under contract to VA.

¹²Institute of Medicine (1999). *Gulf War Veterans: Measuring Health*, Washington, D.C.: National Academy Press, p. 36.

Minutes of RWG meetings from April 1997 forward indicate that they have been attended by a succession of OSAGWI professional staff, as participants or observers, and we have revised the report to reflect this. Nonetheless, the working relationship between these organizations appears far from seamless. For example, RWG felt it necessary to write to OSAGWI to request a briefing on the literature reviews the office had tasked RAND to conduct. Similarly, in a letter to OSAGWI in April 1997, a VA RWG official expressed concerns about the lack of external review for several of OSAGWI's proposed research efforts.

We understand that OSAGWI is not responsible for DOD's medical research programs. As noted in our report, we deliberately adopted a broad scope, to include both research and investigation of exposure scenarios, to comprehensively examine relevant efforts. In any event, some of OSAGWI's projects (listed in app. II) constitute research not only by the dictionary definition that DOD cites but also by DOD's more restrictive criteria.

Whether these undertakings are regarded as research or some other type of endeavor, our interest was in assessing their productivity. Thus, the key point is that most of the contracted projects are completed, but only a handful had been released.

10. While DOD and others have published various assessments of the research program, none of them have directly addressed the status of the research objectives identified in 1995. We requested this information from RWG officials, orally and in writing, and did not receive it. DOD contends that the effectiveness of these research efforts is not yet fully measurable. However, what is needed is not a final judgment but a simple accounting of where federal efforts stand with respect to answering the basic questions identified in 1995.

11. We have not called for an identification of a single unifying case definition or a summary judgment of treatment efficacy for heterogeneous conditions. However, it would seem reasonable to expect an accounting of the status of veterans' health over time and a description of the types of treatments they have received. DOD suggests that it would be unreasonably difficult to provide such information. We note in the text that some basic questions about veterans' health may be addressed by VA's national health survey. However, at this writing, data from the survey have not yet been published. In mid-September 1999, the National Academy of Sciences Institute of Medicine Committee that VA commissioned to study methodological problems issued a report that describes a method of health

assessment. The law requires that VA continue this process by reviewing the methods suggested by IOM and pursuing, to the extent feasible, the collection of appropriate data.

12. With respect to the task order issued under the Management, Organizational, Business Improvement Schedule (MOBIS) contract, OSAGWI does not take issue with our conclusion that the order is outside the scope of the contract. For the reasons stated in the report, we continue to believe that the task order was improper. Therefore, the order should be terminated, if practicable, as we recommended and the office should ensure that any subsequent support contract is properly awarded.

We recognize that OSAGWI relies on contracting professionals outside that office to execute its support contracts. However, that does not absolve the office of all responsibility concerning how its contract support is acquired. At a minimum, OSAGWI is responsible for determining and articulating its requirements, a process that in one instance resulted in the naming of a preferred vendor and in another instance led to an overly broad statement of work. The effect of these practices was to discourage competition for over \$20 million in awards and therefore to risk inefficient use of funds. It is important that both entities that initiate requests for goods and services (for example, OSAGWI) as well as agencies that execute contracts for these goods and services ensure adherence to the statutes and regulations designed to maximize competition.

Comments From the Department of Veterans' Affairs

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF VETERANS AFFAIRS
ASSISTANT SECRETARY FOR PLANNING AND ANALYSIS
WASHINGTON DC 20420

SEP 9 1999

Mr. Kwai-Cheung Chan
Director, Special Studies and Evaluation
National Security and International Affairs Division
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Chan:

This is in response to your draft report, **GULF WAR ILLNESSES: Management Actions Needed to Answer Basic Research Questions** (GAO/NSIAD-99-103). Although we agree with much of the report, we have several concerns regarding portions of GAO's findings, conclusions and recommendations. These concerns preclude us from concurring with recommendations two and three.

The GAO report notes (pages 6 and 10) that many questions about Gulf War veterans remain unanswered, including the prevalence of diagnosed and undiagnosed illnesses, what treatments have been received, and whether Gulf War veterans who have received care in VA facilities are getting better or worse. While complete answers to these questions are not yet available, the Veterans Health Administration (VHA) has taken considerable effort to address these issues. As we have previously reported, VHA has carried out several activities that provide longitudinal information on the health status of Gulf War veterans. This is, however, a highly complex question, and the answers provided are, admittedly, incomplete. The methodology to obtain valid, definitive answers to the questions GAO poses is not insignificant. To obtain advice on the optimal methods to assess the health status of Gulf War veterans, we contracted with the National Academy of Sciences, Institute of Medicine (IOM). The IOM committee established for this project sponsored a workshop in Washington, D.C, on May 7, 1998, and released its Workshop Summary on August 31, 1998. This summary did not contain any conclusions or recommendations. The committee will publish its final report and recommendations in September 1999.

In order to acquire more detailed information about veterans' perceptions of their care, we conducted a detailed Gulf War veteran customer satisfaction survey during the past fiscal year. We intend that this will become a longitudinal feedback mechanism to assess current levels of customer satisfaction with VA care, to measure functional health status, and to assess improvements in these areas. In addition to this survey, VHA's Office of Quality and Performance also conducted Gulf War veteran focus groups to assess further the special needs and concerns of these individuals.

See comment 1.

See comment 2.

2. Mr. Kwai-Cheung Chan

See comment 2.

In further pursuit of identifying the most effective treatment modalities and clinical settings, VA has initiated five clinical demonstration projects at seven VAMCs for case management and multidisciplinary specialized Gulf War clinics. The demonstration projects, which are funded as two-year studies, will support this important effort by using objective outcome measures to assess whether health care and patient satisfaction for Gulf War veterans are improved by multidisciplinary specialized Gulf War clinics or by case management approaches.

See comment 3.

GAO states, "because of the way data on symptoms are recorded in VA and the Department of Defense (DoD) registries, the registries are not good sources of information regarding the prevalence of various symptom clusters among veterans groups." This statement is incorrect. The Registry's inability to determine incidence and prevalence of Gulf War veteran's health problems is unrelated to the manner in which the data are recorded in the database. The Gulf War Health Registries are not adequate for determining the prevalence of symptoms or diagnoses in the Gulf War population because of the self-selected nature of this voluntary health examination program. Although VA's registry is severely limited as a research tool, it has served the purpose for which it was established.

See comments 4-6.

See comment 4.

See comment 5.

See comment 6.

GAO is critical of the coordination between the Persian Gulf Veterans' Coordinating Board's (PGVCB) Research Working Group (RWG) and the Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses (OSAGWI). We take issue with this conclusion for a number of reasons. First, it is important to note that the role of the PGVCB is one of communication and coordination of its member agencies' activities; it does not control these activities. Second, OSAGWI is represented on the RWG's parent organization, the PGVCB, along with the Department of Defense Office of Biomedical Research and Office of Health Affairs. Third, the overwhelming majority of OSAGWI's work has been focused on determination of facts concerning specific incidents of the Gulf War as opposed to research. This work would not be subject to overview by the PGVCB.

See comments 7-9.

See comment 7.

Additionally, GAO inappropriately illustrates the lack of communication and coordination between the RWG and OSAGWI through two contracts. The OSAGWI contract with the RAND Corporation is for literature reviews on various Gulf War topics; VA's contract with the IOM is for an analysis of the scientific literature to determine whether associations exist between Gulf War exposures and health effects. This example is inappropriate for a number of reasons. First, the published RAND reports are made available to the IOM. In fact the IOM has a copy of the RAND report on depleted uranium and the Department of Health and Human Services (HHS) Agency for Toxic Substances and Disease Registry (ATSDR) report on uranium and will review these documents as appropriate. Second, the RAND reports and the IOM committee's study use different

See comment 8.

3. Mr. Kwai-Cheung Chan

See comment 8.

methods, have different goals, and are not duplicative. The Presidential Advisory Committee was aware of the RAND work and still recommended that VA contract with the IOM for its study. An IOM committee will provide a comprehensive review, evaluation, and summary of available scientific/medical information regarding the association between exposure during the Gulf War and adverse health effects experienced by Gulf War veterans. This review will include an assessment of biologic plausibility that exposures, or synergistic effects of combinations of exposures, are associated with illnesses Gulf War veterans experienced. The NAS will make recommendations for additional scientific studies to resolve areas of continued scientific uncertainty related to health consequences. Finally, the IOM study is being carried out under legislative mandates provided in both Public Law 105-368 and Public Law 105-277.

See comment 9.

See comment 10.

While we agree that many questions about Gulf War veterans' symptoms remain unanswered, there is still no evidence that the symptoms reported by veterans constitute a unique disease entity. Consequently, no single case definition is appropriate.

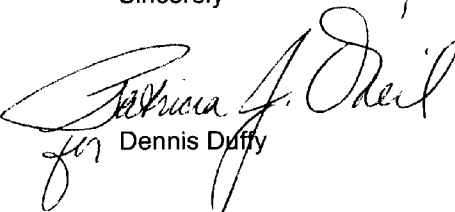
See comment 11.

We concur with recommendation one, that the RWG establish a date in FY 1999 or FY 2000 for publishing its assessment of progress toward addressing the research objectives it identified in 1995. As worded in the draft report, we cannot concur with recommendation two, to complete steps to compile data on the number of veterans with Gulf War illnesses, the progression of their illnesses, the treatments they are receiving, and the success of these treatments. Without clear case definitions the recommendation cannot be implemented as currently worded. GAO should consider revising the recommendation to read, ". . . the number of veterans with unexplained Gulf War illnesses. . . ." This would remove the implied causality associated with the current wording of the recommendation. Finally, we do not concur with recommendation three. As discussed above, the RWG has already provided sufficient information on the scope of activities that it has and continues to coordinate among VA, DoD and HHS.

See comment 12.

Thank you for the opportunity to comment on your draft report.

Sincerely



for Dennis Duffy

GAO Comments

The following is GAO's response to the Department of Veterans' Affairs comments dated September 9, 1999.

1. VA acknowledges that complete answers remain unavailable to the basic questions we identified in this report and in an earlier report (for example, how many veterans have unexplained illnesses and whether ill veterans examined by VA and DOD are better or worse than when they were first seen).¹ A basically satisfactory answer to the question of whether those ill veterans who have registered with VA or DOD are in better or worse health than when first examined involves only a periodic reassessment of their health, which is part of routine medical care.² As we stated when we first made such a recommendation 2 years ago, augmenting the data on the progress of ill Gulf War veterans with comparative data would add valuable information. However, at a minimum, it seems desirable to collect descriptive information on how Gulf War veterans' conditions have improved or worsened. In mid-September 1999, IOM issued its report, which recommended a methodology to VA for measuring veterans' health status (a longitudinal follow-up of a cluster sample of Gulf War veterans with several comparison groups). This approach is consistent with our recommendation that VA and DOD select a strategy for answering this question and compile the appropriate data.

2. Many of the efforts VA cites appear worthwhile, but VA does not assert that any of these have answered or would answer the basic questions we have identified about the prevalence of diagnosed and undiagnosed conditions in Gulf War veterans, the treatments they have received, and the course of any unexplained illnesses. The Veterans' Health Administration's (VHA) intention to collect longitudinal data on these veterans' satisfaction with VHA services may provide a useful monitor of veterans' perceptions. Early findings from this work suggest that Gulf War veterans, as a group,

¹See *Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed* (GAO/NSIAD-97-163), June 23, 1997.

²For example, such an effort has been pursued by one of the VA's Integrated Service Networks. Using a standardized assessment of health-related functioning, the SF-36 from the RAND medical outcomes study, researchers found that the presenting Gulf War veterans scored lower than U.S. norms on all dimensions of health status and that baseline scores were significantly different from 6 month follow-up. See Powell-Cope, G. M. & Roswell, R. (1999). Health Status of Gulf War Veterans in VISN 8. The Research Working Group, Persian Gulf Veterans Coordinating Board, *Conference on Federally Sponsored Gulf War Veterans' Illnesses Research*, Washington, D.C.: PGVCB/RWG, p. 32.

were somewhat less satisfied with VHA services than other veteran groups. VHA's efforts to clarify the reasons for this through the use of focus groups are also appropriate. Similarly, the health services research efforts that VA identifies may help improve service delivery but do not appear suited to developing much longitudinal information because the projects are funded for only 2 years.

3. Among the conclusions the NIH Working Group reached in 1994 was that, "It is important that a more accurate estimate of the symptom prevalence be established." In support of our finding that basic information on the prevalence of various symptom clusters remains unavailable, we note that VA and DOD registries of examined Gulf War veterans also do not provide sufficient data for determining which of various symptom clusters deserve the closest attention. We agree that the registries may be valuable for other purposes and that there are additional reasons that they might be imperfect research tools. While the VA's national health survey has collected much of the symptom data sought by the NIH group, its results remained unpublished at the close of our review.

4. In support of its objection to our criticism of the coordination between the PGVCB RWG and the Office of the Special Assistant, VA notes that the role of the PGVCB is one of communication and coordination of its member agencies' activities; it does not control these activities. For this reason, our draft report noted that PGVCB has no budgetary authority. Nonetheless, part of the function of communication and coordination is to reach agreement on a plan of action to optimize resources while meeting sometimes varied needs for information. We observed that some projects sponsored by agency members of the RWG are duplicative (see our comment 9 in app. IV.)

5. In support of its objection to our criticism of the coordination between the PGVCB's RWG and the Office of the Special Assistant, VA notes that OSAGWI is represented on the RWG's parent organization, the Coordinating Board, along with other DOD elements. We have revised the report to reflect that professional staff from OSAGWI did attend RWG meetings, as participants or observers, beginning in April 1997. We have not asserted that a coordination mechanism is missing; our criticism is related to the effectiveness of this mechanism in eliminating duplicative expenditures and ensuring uniformly high confidence across agencies in the research activities undertaken.

6. While most of OSAGWI's expenditures appear to be focused on the investigation of specific incidents for the potential exposures that might have resulted, which would be germane to epidemiological researchers, OSAGWI officials identified \$13.3 million, a substantial amount of the office's expenditures, as being devoted to research. It is worth noting that this amount, while it represents a minority of OSAGWI's budget, exceeds the total of VA and CDC Gulf War research expenditures over the period we examined.

7. First, appendix II of the draft report noted that only four of the nine RAND reports submitted for interagency review had actually reached publication by mid-1999 and that publication had, in some instances, occurred over a year following submission. After receiving DOD's comments on our report, RAND's report on pyridostigmine bromide was released 16 months after its submission to interagency review in June 1998. Similarly, RAND's report on stress was published approximately a year after submission for review, and its report on chemical and biological warfare agents was submitted for interagency review 15 months ago. Thus, delaying the release of these documents to IOM until publication occurs does not seem an effective means of coordinating two such closely linked tasks.

Second, it is important to note that the Agency for Toxic Substances and Disease Registry's report on uranium (including depleted uranium) was made available for public comment on October 17, 1997 (the public comment period ended on Feb. 17, 1998, and revision was begun based on comments received). Thus, the need for an additional review of depleted uranium by RAND in 1997 was questionable. The RAND review was not submitted until August of 1998, after the Agency review had been issued in draft form.³ We have added a discussion of this matter to our report.

8. VA asserts that the goals and methods of these two studies are different but does not explain how they are different. Because IOM will not be conducting original research to make its determinations, it will also rely on existing literature. Material distributed by IOM in connection with a recent meeting of its Committee on Health Effects Associated with Exposures During the Gulf War indicates that, "The purpose of this project would be to conduct a review of the scientific and medical literature regarding adverse

³See Agency for Toxic Substances and Disease Registry (Sept. 1997). Draft Toxicological Profile for Uranium. Atlanta, GA:U.S. Dept. of Health and Human Services, PHS/ATSDR.

health effects associated with exposures experienced during the Persian Gulf War.” Similarly, the preface to one of RAND’s literature reviews notes, “The reviews are intended principally to summarize the scientific literature on the known health effects of given exposures to these risk factors.” Accordingly, we find little distinction between these two activities in terms of purpose or basic methodology.

9. The issue we are raising is not whether IOM’s work ought to have been initiated but that its work has not benefited from coordination with RAND’s to save time and money in accomplishing a goal that is widely regarded as important. Similarly, RAND’s work was not coordinated with that of CDC’s Agency for Toxic Substances and Disease Registry.

10. Even if the symptoms reported by Gulf War veterans are not confined to these veterans, their increased frequency among Gulf War veterans needs to be explained. Our report does not suggest that a single case definition is appropriate; we note simply that RWG has not endorsed one or more case definitions that might focus research on veterans’ undiagnosed symptoms.

11. This recommendation has been reworded to refer to “the number of Gulf War veterans with unexplained illnesses.” We understand that, in implementing the recommendation, it may be appropriate to characterize unexplained illnesses using some groupings or working case definitions for the purposes of counting.

12. We made this recommendation to prompt organizations to work more closely on behalf of veterans suffering from these illnesses. We believe that greater cooperation, exchange of information, and coordination will help expedite the process and help find solutions the veterans need. While VA indicates that RWG has provided sufficient information on the scope of activities it continues to coordinate among DOD, VA, and HHS, we found substantially similar activities that fell outside this scope. In addition, we find nothing in the law that would limit the Group’s coordinating efforts to this scope of activities.

Comments From the Centers for Disease Control and Prevention

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 20 1999

Mr. Kwai-Cheung Chan
Director, Special Studies and Evaluation
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Chan:

Thank you for the opportunity to review the GAO draft report, "Gulf War Illnesses: Management Actions Needed to Answer Basic Research Questions." The Centers for Disease Control and Prevention generally concurs with the report. For your consideration, the following are comments on the sections that deal directly with activities related to the Department of Health and Human Services.

1. In discussing the success of the federal government in documenting the symptoms of Gulf War veterans, the report does not acknowledge the information learned from two important CDC-funded studies, the Health Assessment of Gulf War Veterans From Iowa and the CDC Air Force study.

- The Iowa study was the first population-based epidemiologic study to evaluate the health consequences of the Gulf War. The 3,695 subjects who completed this study were selected from a larger population of almost 29,000 military personnel who listed Iowa as their home of record. Furthermore, the subjects in this study were specifically selected to represent individuals from all four branches of the military, and include both regular military personnel and National Guard and reservists. The interviews for the study were conducted by telephone. This resulted in a high rate of participation. Seventy-six percent of the eligible study subjects completed the detailed interviews; the response rate was 91% among persons contacted by telephone. This study is also one of the first controlled epidemiological studies to evaluate the health consequences of the Gulf War. The study included a carefully selected comparison group of military personnel who were not deployed to the Persian Gulf but who served during the time of the Gulf War. The Iowa Study found that the Gulf War military personnel were more likely than those who did not serve in the Gulf War to report symptoms suggestive of cognitive dysfunction, depression, chronic fatigue, post-traumatic stress disorder, and respiratory illness (asthma and bronchitis). The conditions identified in this study appear to have had a measurable impact on the functional activity and daily lives of these Gulf War veterans. Among Gulf War veterans, minimal differences were observed between the National Guard or reserve troops and the regular military personnel.

See comment 1.

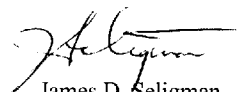
**Appendix VI
Comments From the Centers for Disease
Control and Prevention**

Page 2 - Kwai-Cheung Chan

- Likewise, the CDC Air Force study has significantly contributed to our understanding of the health consequences of the Gulf War. This study organized symptoms reported by Air Force Gulf War veterans into a case definition, characterized clinical features, and evaluated risk factors. The cross-sectional questionnaire was sent to 3723 currently active volunteers from four Air Force populations. Clinical evaluations were performed on 158 Gulf War veterans from one unit, irrespective of health status. A case was defined as having one or more chronic symptoms from at least 2 of 3 categories (fatigue, mood-cognition and musculoskeletal) and was further characterized as mild-to-moderate or severe depending on the severity of the symptoms. The prevalence of mild-to-moderate and severe cases were 39% and 6%, respectively, among 1155 Gulf War veterans versus 14% and 0.7% among 2520 non deployed veterans. Fifty-nine (37%) clinically evaluated Gulf War veterans were noncases, 86 (54%) were mild-to-moderate cases and 13 (8%) were severe cases. The key observation of the study was that Air Force Gulf War veterans were significantly more likely to meet criteria for severe and mild-to-moderate illness than were non deployed personnel. There was no association between the chronic multisymptom illness and risk factors specific to combat in the Gulf War (month of season of deployment, duration of deployment, duties in the Gulf War, direct participation in combat, or locality of Gulf War service). The finding that 15% of non deployed veterans also met illness criteria was equally important and suggest that the multisymptom illness observed in this population is not unique to Gulf War service. The clinical evaluation component of the study found that neither mild-to-moderate nor severe cases were associated with clinically significant physical examination or routine laboratory test abnormalities. However, Gulf War veterans classified as having mild-to-moderate and severe illness had a significant decrease in functioning and well-being compared with noncases.

2. Page 8, para. 1: The draft report states that 47% of Gulf War research projects cataloged by the Research Working Group were overdue in December 1998. The report cites CDC's Health Assessment of Gulf War Veterans from Iowa as an example of a project that is overdue due to the estimated completion date being extended. It should be noted that the original telephone component of the study was completed and the results published within the projected time frame. After the original telephone study was completed, a decision was made to add on a follow-up component in order to validate the self-report data. The time required to obtain OMB clearance and collect and analyze the data for this follow-up component required that the completion date for the Iowa study be extended.

If you have any questions concerning these comments, please contact Carolyn Russell, Director, Management Analysis and Services, (404) 639-4002.



James D. Seligman
Acting Director, Office of
Program Support

See comment 2.

GAO Comments

The following is GAO's response to the Centers for Disease Control and Prevention's comments dated August 20, 1999.

1. CDC's Air Force study was cited in appendix III of our draft report along with the case definition it developed as one of a set of overlapping working case definitions that have been advanced since 1994. We have added information about these studies and their findings to the final report and have discussed them more fully in our response to agency comments and also in our more detailed response to DOD's comments (see comment 6 in app. IV).
2. Our draft report noted that the extensions discussed were partially attributed to efforts to incorporate additional data. We have added the word "additional" before "follow-up" to specifically clarify that the extension of the Iowa project was to provide for work not initially anticipated, not to allow additional time for work already planned.

GAO Contacts and Staff Acknowledgments

GAO Contacts

Sushil K. Sharma (202) 512-3460
Betty Ward-Zukerman (202) 512-2732

Acknowledgments

In addition to those named above, Margaret Best, John Carter, Howard Deshong, and William Woods made key contributions to this report.

Related GAO Products

Gulf War Illnesses: Procedural and Reporting Improvements Are Needed in DOD's Investigative Processes ([GAO/NSIAD-99-59](#), Feb. 26, 1999).

Acquisition Reform: Multiple-Award Contracting at Six Federal Organizations ([GAO/NSIAD-98-215](#), Sept. 30, 1998).

VA Health Care: Better Integration of Services Could Improve Gulf War Veterans' Care ([GAO/HEHS-98-197](#), Aug. 19, 1998).

Role of the Persian Gulf Veterans' Coordinating Board in Scientific Evaluation of Research Proposals and the Funding Recommendations Made by Its Research Working Group ([GAO/NSIAD-98-170R](#), Aug. 10, 1998).

Gulf War Veterans: Limitations of Available Data for Accurately Determining the Incidence of Tumors ([GAO/T-NSIAD-98-186](#), May 14, 1998).

VA Health Care: Persian Gulf Dependents' Medical Exam Program Ineffectively Carried Out ([GAO/HEHS-98-108](#), Mar. 31, 1998).

Gulf War Veterans: Incidence of Tumors Cannot Be Reliably Determined From Available Data ([GAO/NSIAD-98-89](#), Mar. 3, 1998).

Gulf War Illnesses: Federal Research Strategy Needs Reexamination ([GAO/T-NSIAD-98-104](#), Feb. 24, 1998).

Gulf War Illnesses: Research, Clinical Monitoring, and Medical Surveillance ([GAO/T-NSIAD-98-88](#), Feb. 5, 1998).

Veterans' Benefits: Improvements Made to Persian Gulf Claims Processing ([GAO/T-HEHS-98-89](#), Feb. 5, 1998).

Gulf War Illnesses: Public and Private Efforts Relating to Exposures of U.S. Personnel to Chemical Agents ([GAO/NSIAD-98-27](#), Oct. 15, 1997).

Gulf War Illnesses: Reexamination of Research Emphasis and Improved Monitoring of Clinical Progress Needed ([GAO/T-NSIAD-97-191](#), June 25, 1997).

Gulf War Illnesses: Enhanced Monitoring of Clinical Progress and of Research Priorities Needed ([GAO/T-NSIAD-97-190](#), June 24, 1997).

Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed ([GAO/NSIAD-97-163](#), June 23, 1997).

VA Health Care: Observations on Medical Care Provided to Persian Gulf Veterans ([GAO/T-HEHS-97-158](#), June 19, 1997).

Chemical and Biological Defense: Protection of Critical Overseas Ports and Airfields Remains Largely Unaddressed ([GAO/NSIAD-97-9](#), June 13, 1997).

Operation Desert Storm: Evaluation of the Air Campaign ([GAO/NSIAD-97-134](#), June 12, 1997).

Defense Health Care: Medical Surveillance Has Improved Since the Gulf War, but Results in Bosnia Are Mixed ([GAO/NSIAD-97-136](#), May 13, 1997).

Veterans' Compensation: Evidence Considered in Persian Gulf War Undiagnosed Illness Claims ([HEHS-96-112](#), May 28, 1996).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems ([GAO/NSIAD-96-103](#), Mar. 29, 1996).

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are \$2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary, VISA and MasterCard credit cards are accepted, also.

Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

**U.S. General Accounting Office
P.O. Box 37050
Washington, DC 20013**

or visit:

**Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC**

**Orders may also be placed by calling (202) 512-6000
or by using fax number (202) 512-6061, or TDD (202) 512-2537.**

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

or visit GAO's World Wide Web Home Page at:

<http://www.gao.gov>

**United States
General Accounting Office
Washington, D.C. 20548-0001**

**Official Business
Penalty for Private Use \$300**

Address Correction Requested

<p>Bulk Rate Postage & Fees Paid GAO Permit No. GI00</p>

