

GAO

Report to the Chairman, Subcommittee
on National Security, Emerging Threats,
and International Relations, Committee
on Government Reform, House of
Representatives

June 2004

DEPARTMENT OF
VETERANS AFFAIRS

Federal Gulf War
Illnesses Research
Strategy Needs
Reassessment



G A O

Accountability * Integrity * Reliability



Highlights of [GAO-04-767](#), a report to the Chairman, Subcommittee on National Security, Emerging Threats, and International Relations, Committee on Government Reform, House of Representatives

Why GAO Did This Study

More than a decade after the 1991 Persian Gulf War, there is continued interest in the federal response to the health concerns of Gulf War veterans. Gulf War veterans' reports of unexplained illnesses and possible exposures to various health hazards have prompted numerous federal research projects on Gulf War illnesses. This research has been funded primarily by the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the Department of Health and Human Services. GAO is reporting on (1) the status of research and investigations on Gulf War illnesses, (2) the efforts that have been made by VA and DOD to monitor cancer incidence among Gulf War veterans, and (3) VA's communication and collaboration with the Research Advisory Committee on Gulf War Veterans' Illnesses (RAC).

What GAO Recommends

GAO recommends that the Secretary of VA conduct a reassessment of the federal Gulf War illnesses research strategy, ensure that a liaison who is knowledgeable about Gulf War illnesses research is appointed to routinely share information with RAC, and ensure that VA's research offices collaborate with RAC on Gulf War illnesses research program development activities. VA concurred with the report's recommendations and cited several actions it has initiated to address them.

www.gao.gov/cgi-bin/getrpt?GAO-04-767.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

DEPARTMENT OF VETERANS AFFAIRS

Federal Gulf War Illnesses Research Strategy Needs Reassessment

What GAO Found

Most federally funded Gulf War illnesses research projects and investigations are complete, but VA—the agency with lead responsibility for coordination of Gulf War illnesses issues—has not yet analyzed the latest research findings to identify whether there are gaps in current research or to identify promising areas for future research. As of September 2003, about 80 percent of the 240 federally funded medical research projects for Gulf War illnesses had been completed. In recent years, VA and DOD funding for this research has decreased, federal research priorities have changed, and interagency coordination of Gulf War illnesses research has waned. In addition, VA has not reassessed the extent to which the collective findings of completed Gulf War illnesses research projects have addressed key research questions. The only assessment of progress in answering these research questions was published in 2001, when findings from only about half of all federally funded Gulf War illnesses research were available. Moreover, it did not identify whether there were gaps in existing Gulf War illnesses research or promising areas for future research. This lack of comprehensive analysis leaves VA at greater risk of failing to answer unresolved questions about causes, course of development, and treatments for Gulf War illnesses. In a separate effort, DOD has conducted 50 investigations since 1996 on potential hazardous exposures during the Gulf War. Generally, these investigations concluded that there were limited exposures by troops to some hazards and, at most, limited short- or long-term adverse effects expected from these exposures. As of April 2003, all investigations were complete.

Federal agencies have funded seven research projects related to cancer incidence among Gulf War veterans. However, several limitations exist that affect research related to cancer incidence. For example, some cancers may take many years to develop and be detected. In addition, some research projects studying cancer incidence have not studied enough Gulf War veterans to reliably assess cancer incidence. Research may also be impeded by incomplete federal data on the health characteristics of Gulf War veterans.

RAC's efforts to provide advice and make recommendations on Gulf War illnesses research to the Secretary of VA may have been hampered by VA senior administrators' incomplete or unclear information sharing and limited collaboration on research initiatives and program planning. VA and RAC are exploring ways to improve collaboration, including VA's hiring of a senior scientist who would both guide VA's Gulf War illnesses research and serve as the agency's liaison for routine updates to the advisory committee. However, most of these changes had not been finalized at the time of our review.

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Abbreviations

CRADO	Chief Research and Development Officer
DHSD	Deployment Health Support Directorate
DHWG	Deployment Health Working Group
DOD	Department of Defense
GWV	Gulf War veterans
HEC	VA/DOD Health Executive Council
HHS	Department of Health and Human Services
MVHCB	Military Veterans Health Coordinating Board
NIH	National Institutes of Health
NSTC	National Science and Technology Council
OSAGWI	Office of Special Assistant for Gulf War Illnesses
OSAGWI-MRMD	Office of Special Assistant for Gulf War Illnesses Medical Readiness and Military Deployments
PGIIT	Persian Gulf Illnesses Investigation Team
PGIRCC	Persian Gulf Interagency Research Coordinating Council
PGVCB	Persian Gulf Veterans Coordinating Board
RAC	Research Advisory Committee on Gulf War Veterans' Illnesses
RWG	Research Working Group
VA	Department of Veterans Affairs

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United States General Accounting Office
Washington, DC 20548

June 1, 2004

The Honorable Christopher Shays
Chairman
Subcommittee on National Security,
Emerging Threats, and International Relations,
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

More than a decade after the end of the 1991 Persian Gulf War, there is continued interest in the federal government's response to the health concerns of Gulf War veterans. While about 700,000 U.S. military personnel were deployed during this conflict, casualties were relatively light compared with previous major conflicts. However, approximately 80,000 veterans have reported various symptoms in the years following the war, and scientists have agreed that many veterans have unexplained illnesses. Gulf War illnesses are characterized by one or more symptoms that do not conform to a characteristic diagnosis. Such symptoms commonly include fatigue, muscle and joint pains, headaches, memory loss, skin rash, diarrhea, and sleep disturbances. In addition to concerns about unexplained illnesses, many Gulf War veterans also have elevated concerns that possible exposures to chemical or biological warfare agents, or environmental contaminants, may be associated with an increased risk of developing cancer. Past research projects have found associations between some of these substances and different types of cancers.

Gulf War veterans' reports of illnesses have prompted numerous federal research projects on the nature, extent, and treatment of Gulf War illnesses. Federal Gulf War illnesses research projects have been funded primarily by the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the Department of Health and Human Services (HHS). Each agency separately sponsors and funds research projects, though a few are conducted jointly. In 1993, the President made the Secretary of VA responsible for coordinating research activities undertaken or funded by the executive branch of the federal government on the health consequences of service in the Gulf War. In 2002, a congressionally mandated federal advisory committee—the VA Research Advisory Committee on Gulf War Veterans' Illnesses (RAC)—was established to provide advice on federal Gulf War illnesses research needs and priorities

to the Secretary of VA. The committee is made up of members of the general public, including non-VA researchers and veterans' advocates.

Separately from this research, DOD has conducted investigations on specific events that took place during the Gulf War to identify possible exposures to potentially hazardous chemical agents, such as sarin, mustard, and benzyl bromide. In addition, DOD has conducted investigations of potential occupational and environmental hazards, including depleted uranium from munitions, smoke from oil well fires, pesticides, petroleum, and fuels. DOD has published a number of reports that discuss the findings of these Gulf War investigations.

Because of these concerns, we are reporting on (1) the status of federal research and investigations on Gulf War illnesses, (2) the efforts that have been made by VA and DOD to monitor cancer incidence among Gulf War veterans, and (3) VA's communication and collaboration with RAC.

To examine these issues, we interviewed senior officials within VA and DOD and senior managers with each agency's relevant research offices. We analyzed pertinent agency documents, including annual reports to congressional committees describing research priorities, ongoing and completed projects, and agency funding. Additionally, we interviewed RAC officials, attended a RAC meeting, and reviewed RAC reports and recommendations. We conducted our work from September 2003 through May 2004 in accordance with generally accepted government auditing standards. (See app. I for further detail.)

Results in Brief

While the federal focus on Gulf War-specific research has diminished, VA—the agency with lead responsibility for coordination of Gulf War illnesses issues—has not yet analyzed the latest research findings to identify whether there are gaps in current research or to identify promising areas for future research. As of September 2003, about 80 percent of the 240 federally funded medical research projects for Gulf War illnesses had been completed. In recent years, VA and DOD have decreased their expenditures on Gulf War illnesses research and have expanded the scope of their medical research programs to incorporate the long-term health effects of all hazardous deployments. Interagency committees formed by VA to coordinate federal Gulf War illnesses research evolved to reflect these changing priorities, but these entities have ultimately been dissolved or have become inactive. In addition, VA has not reassessed the extent to which the collective findings of completed Gulf War illnesses research projects have addressed key

research questions. The only assessment of progress in answering these research questions was published in 2001, when findings from only about half of all federally funded Gulf War illnesses research were available. As a result, VA has not determined whether previously identified research questions have been answered or whether they remain relevant. This lack of comprehensive analysis leaves VA at greater risk of failing to answer unresolved questions about causes, course of development, and treatments for Gulf War illnesses. In a separate effort, DOD has conducted 50 investigations since 1996 on potential hazardous exposures during the Gulf War. Generally, these investigations concluded that there were limited exposures by troops to some hazards and, at most, limited short- or long-term adverse effects expected from these exposures. As of April 2003, all investigations were complete.

Federal agencies have funded seven research projects related to cancer incidence among Gulf War veterans. However, several limitations exist that affect research related to cancer incidence. For example, some cancers may take many years to develop and be detected. In addition, some research projects have not studied enough Gulf War veterans to reliably assess cancer incidence. Research may also be impeded by incomplete federal data on the health characteristics of Gulf War veterans.

RAC's efforts to provide advice and make recommendations on Gulf War illnesses research may have been hampered by VA senior administrators' incomplete or unclear information sharing and limited collaboration on Gulf War illnesses research initiatives and program planning. For example, VA failed to inform RAC about its 2002 major research program announcement that included Gulf War illnesses research. Similarly, VA did not seek RAC's review of a draft of the 2002 annual report to congressional committees describing current federally funded Gulf War illnesses research. VA and RAC are exploring ways to improve information sharing, including VA's hiring of a senior scientist who would both guide VA's Gulf War illnesses research and serve as the agency's liaison for routine updates to RAC. However, most of these changes had not been finalized at the time of our review.

We are making recommendations to the Secretary of VA to improve federal efforts to plan and coordinate Gulf War illnesses research. Specifically, we recommend that VA conduct a reassessment of the federal Gulf War illnesses research strategy to ensure its continued validity and to identify promising areas for future research. We also recommend that VA improve its sharing of research information and its collaboration with RAC.

In commenting on a draft of this report, VA concurred with the report's recommendations and said that it has begun a preliminary assessment of the federal Gulf War illnesses research strategy, including an evaluation of the 21 key research questions. The agency also noted that it has undertaken various steps, such as coordinating its most recent request for Gulf War research applications with RAC, in order to better collaborate with the advisory committee.

Background

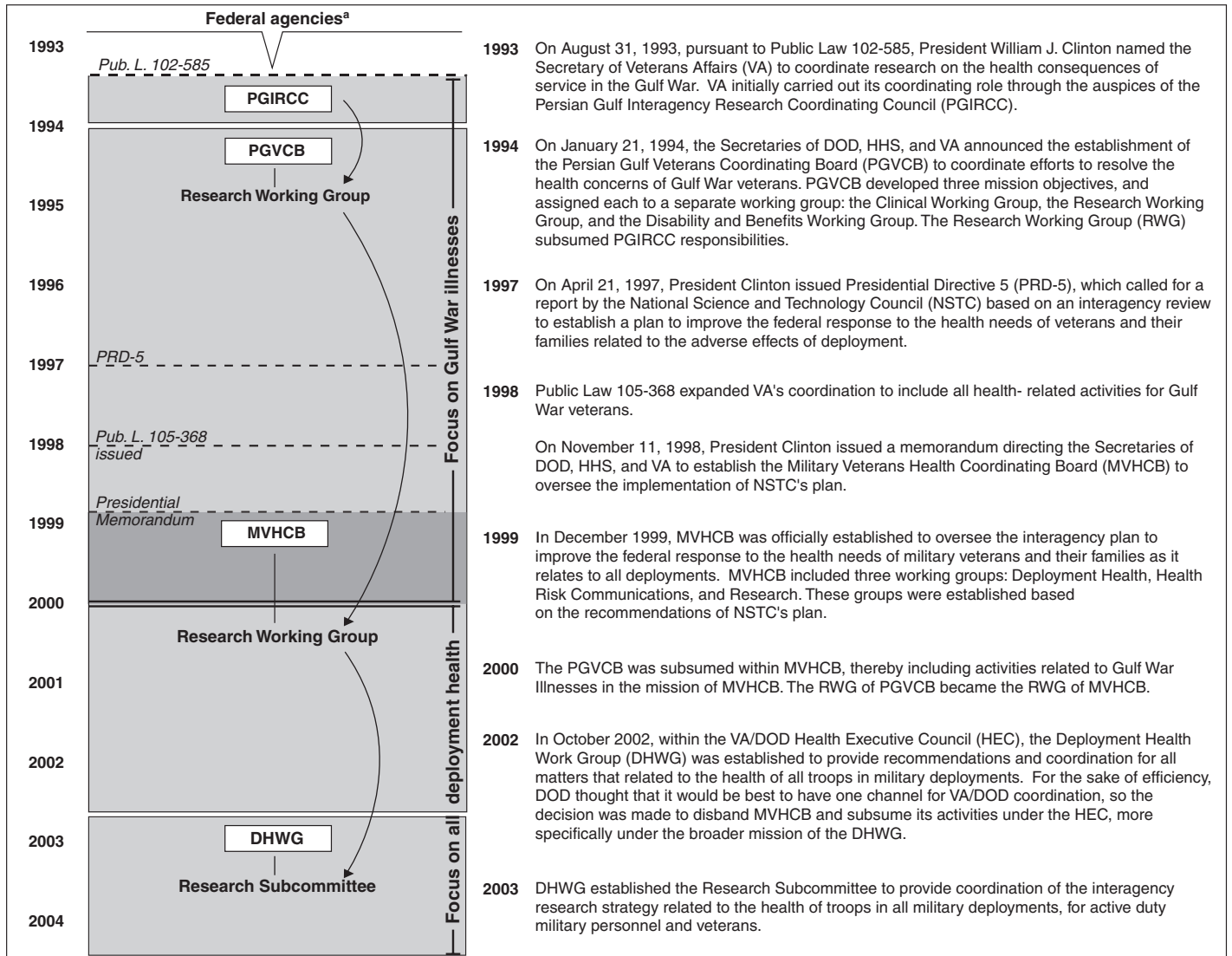
Following Iraq's invasion of Kuwait in August 1990, the United States and other allied nations sent troops to the Persian Gulf region in Operation Desert Shield. In the winter of 1991, the allied forces attacked Iraq in an air campaign and subsequent invasion by ground forces (Operation Desert Storm). Despite the harsh environment, illness, injury, and death rates among approximately 700,000 U.S. military personnel were significantly lower than in previous major conflicts. Yet, shortly after the war, some veterans began reporting health problems that they believed might be due to their participation in the war. VA, DOD, HHS, and other federal agencies initiated research and investigations into these health concerns and the consequences of possible hazardous exposures.

In 1993, the President designated VA as the lead coordinator of research activities on the health consequences of service in the Gulf War. Subsequently, in 1998, the Congress expanded VA's coordination to include all Gulf War health-related activities. These activities include ensuring that the findings of all federal Gulf War illnesses research are made available to the public and that federal agencies coordinate outreach to Gulf War veterans in order to provide information on potential health risks from service in the Gulf War and corresponding services or benefits. The Secretary of VA is required to submit an annual report on the results, status, and priorities of federal research activities related to the health consequences of military service in the Gulf War to the Senate and House Veterans' Affairs Committees. VA has provided these reports to congressional committees since 1995. In May 2004, VA issued its annual report for 2002.¹ VA has carried out its coordinating role through the auspices of interagency committees, which have changed over time in concert with federal research priorities and needs. The mission of these

¹See Deployment Health Working Group Research Subcommittee, U.S. Department of Veterans Affairs, *Annual Report to Congress: Federally Sponsored Research on Gulf War Veterans' Illnesses for 2002* (Washington, D.C.: 2004).

interagency committees has evolved to include coordination for research on all hazardous deployments, including but not limited to the Gulf War. (See fig. 1.)

Figure 1: Evolution of Interagency Committees That Coordinated Federal Gulf War Illnesses Research from 1993 through 2004



Indicates length of time
 Indicates overlap of major committees or councils

Source: VA.

Note: GAO analysis of VA data, public laws, and presidential directives.

^aFederal agencies are VA, DOD, and HHS.

Federal research efforts for Gulf War illnesses have been guided by questions established by the interagency Research Working Group (RWG), which was initially established under the Persian Gulf Veterans Coordinating Board (PGVCB) to coordinate federal research efforts. From 1995 through 1996, RWG identified 19 major research questions related to illnesses in Gulf War veterans. In 1996, the group added 2 more questions regarding cancer risk and mortality rates to create a set of 21 key research questions that serves as an overarching strategy in guiding federal research for Gulf War illnesses. (See app. II for the list of key questions.) The 21 research questions cover the extent of various health problems, exposures among the veteran population, and the difference in health problems between Gulf War veterans and control populations. In 1998, RWG expanded federal Gulf War illnesses research priorities to include treatment, longitudinal follow-up of illnesses, disease prevention, and improved hazard assessment; however, RWG did not add any new research questions. With regard to veterans' health status, the research questions cover the prevalence among veterans and control populations of

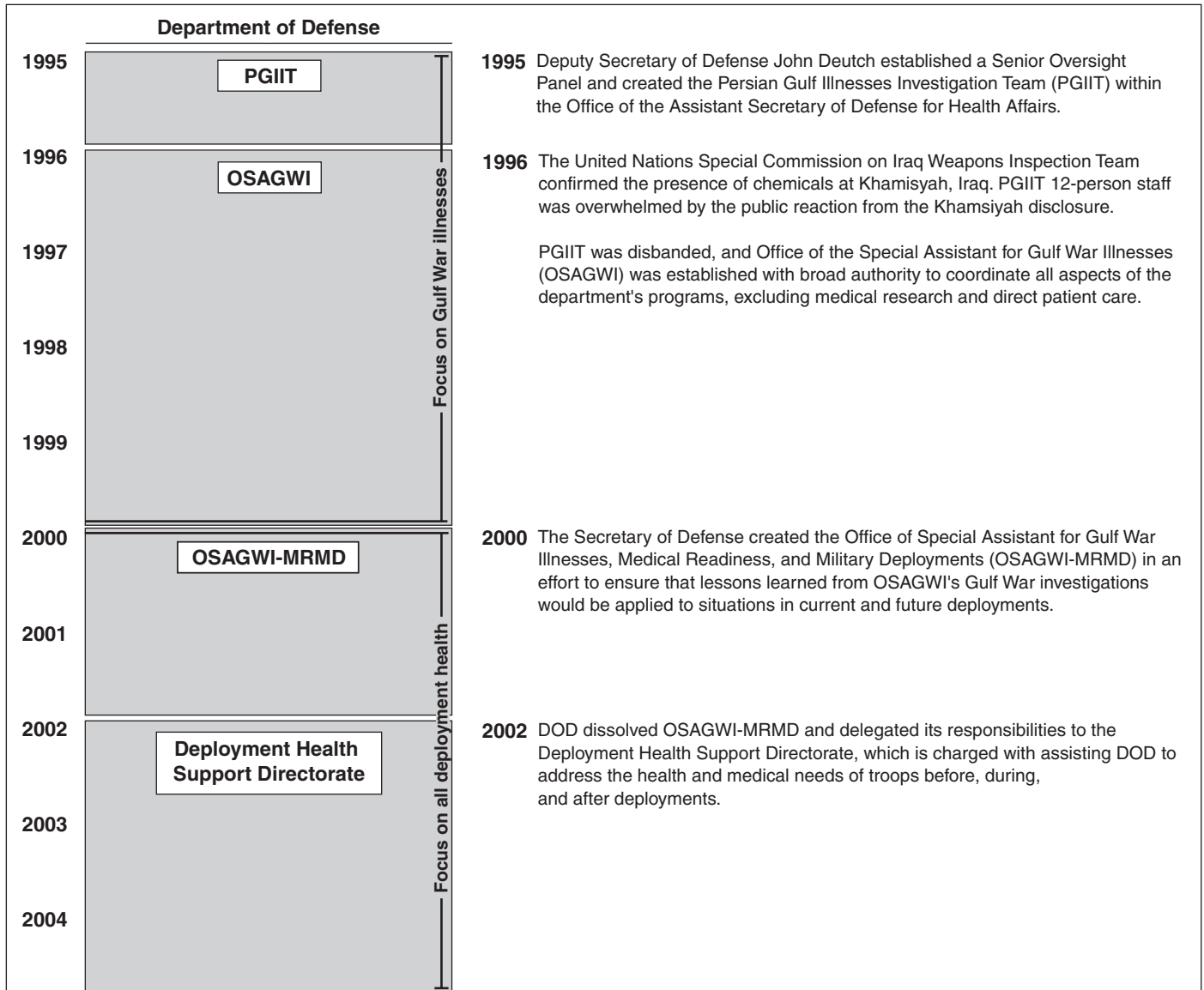
- symptoms,
- symptom complexes,
- illnesses,
- altered immune function or host defense,
- birth defects,
- reproductive problems,
- sexual dysfunction,
- cancer,
- pulmonary symptoms,
- neuropsychological or neurological deficits,
- psychological symptoms or diagnoses, and
- mortality.

With regard to exposure, the research questions cover

- *Leishmania tropica* (a type of parasite),
- petroleum,
- petroleum combustion products,
- specific occupational/environmental hazards (such as vaccines and depleted uranium),
- chemical agents,
- pyridostigmine bromide (given to troops as a defense against nerve agents), and
- psychophysiological stressors (such as exposure to extremes of human suffering).

Separately from these research efforts, DOD is responsible for investigating and reporting incidents of possible chemical and biological agent exposures and other potential occupational and environmental hazards. Within DOD, the entities responsible for overseeing Gulf War exposure investigations have also evolved over time. (See fig. 2.)

Figure 2: DOD Entities Responsible for Gulf War Exposure Investigations from 1995 through 2004



1995 Deputy Secretary of Defense John Deutch established a Senior Oversight Panel and created the Persian Gulf Illnesses Investigation Team (PGIIT) within the Office of the Assistant Secretary of Defense for Health Affairs.

1996 The United Nations Special Commission on Iraq Weapons Inspection Team confirmed the presence of chemicals at Khamisyah, Iraq. PGIIT 12-person staff was overwhelmed by the public reaction from the Khamsiyah disclosure.

PGIIT was disbanded, and Office of the Special Assistant for Gulf War Illnesses (OSAGWI) was established with broad authority to coordinate all aspects of the department's programs, excluding medical research and direct patient care.

2000 The Secretary of Defense created the Office of Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments (OSAGWI-MRMD) in an effort to ensure that lessons learned from OSAGWI's Gulf War investigations would be applied to situations in current and future deployments.

2002 DOD dissolved OSAGWI-MRMD and delegated its responsibilities to the Deployment Health Support Directorate, which is charged with assisting DOD to address the health and medical needs of troops before, during, and after deployments.

Indicates length of time

Source: DOD.

Note: GAO analysis of DOD data.

In 2002, VA established RAC to provide advice to the Secretary of VA on proposed research relating to the health consequences of military service in the Gulf War.² RAC, which is composed of members of the general public, including non-VA researchers and veterans' advocates, was tasked with assisting VA in its research planning by exploring the entire body of Gulf War illnesses research, identifying gaps in the research, and proposing potential areas of future research. VA provides an annual budget of about \$400,000 for RAC, which provides salaries for two full-time employees and one part-time employee and supports committee operating costs. RAC's employees include a scientific director and support staff who review published scientific literature and federal research updates and collect information from scientists conducting relevant research.³ RAC's staff provide research summaries for discussion and analysis to the advisory committee through monthly written reports and at regularly scheduled meetings. RAC holds public meetings several times a year at which scientists present published and unpublished findings from Gulf War illnesses research. In 2002, RAC published a report with recommendations to the Secretary of VA. It expects to publish another report soon.

²VA was required to establish RAC by the Veterans Programs Enhancement Act of 1998, Pub. L. No. 105-368, § 104, 112 Stat. 3315, 3323.

³RAC's scientific director, a research associate professor, is also an appointed member of RAC.

Most Federally Funded Gulf War Illnesses Research Projects and Investigations Are Complete, but VA Has Not Collectively Analyzed Research Findings to Determine the Status of Key Research Questions

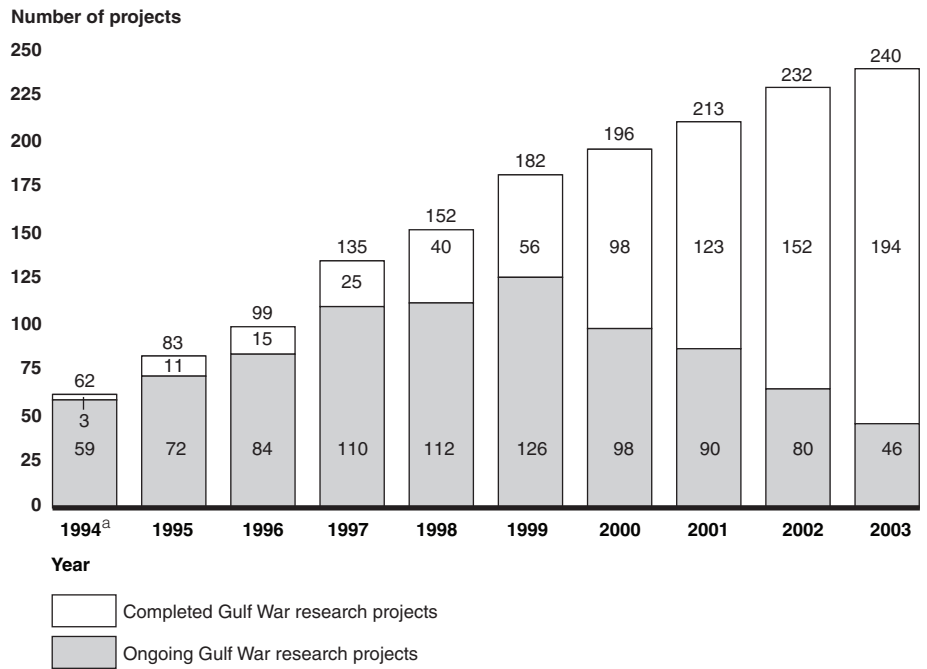
More than 80 percent of the 240 federally funded Gulf War illnesses research projects have been completed. In recent years, funding for this research has decreased, federal research priorities have expanded to incorporate the long-term health effects of all hazardous deployments, and interagency coordination of Gulf War illnesses research has waned. In addition, with respect to the federal research strategy, VA has not reassessed the research findings to determine whether the 21 key research questions have been answered or to identify the future direction of federal research in this area. In a separate but related effort, as of April 2003, all of DOD's Gulf War investigations were complete.

Most Federally Funded Gulf War Illnesses Research Projects Are Complete, and Funding Is Decreasing as Research Priorities Broaden

Since 1991, 240 federally funded research projects have been initiated by VA, DOD, and HHS to address the health concerns of individuals who served in the Gulf War. As of September 2003, 194 of the 240 federal Gulf War illnesses research projects (81 percent) had been completed; another 46 projects (19 percent) were ongoing.⁴ (See fig. 3.)

⁴Annual reports to congressional committees submitted by VA on federally sponsored research on Gulf War veterans' illnesses identify projects as completed when total project funding has concluded.

Figure 3: Cumulative Number of Ongoing and Completed Federal Gulf War Illnesses Research Projects by Year



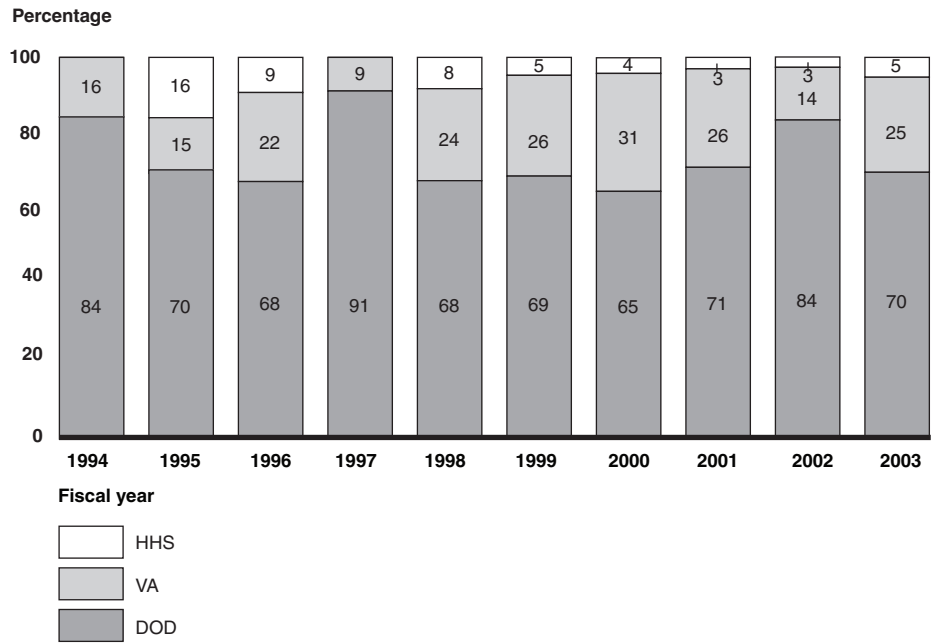
Source: VA.

Note: GAO analysis of VA data.

^aThis total includes ongoing projects from 1991 through 1994.

From 1994 through 2003, VA, DOD, and HHS collectively spent a total of \$247 million on Gulf War illnesses research. DOD has provided the most funding for Gulf War illnesses research, funding about 74 percent of all federal Gulf War illnesses research within this time frame. Figure 4 shows the comparative percentage of funding by these agencies for each fiscal year since 1994.

Figure 4: Funding Share for Gulf War Illnesses Research by Agency and Fiscal Year

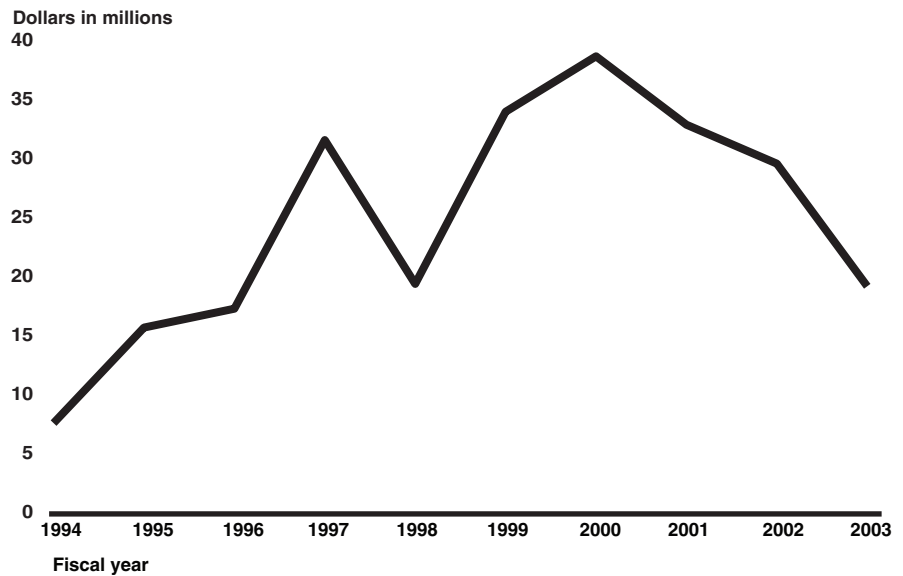


Source: VA.

Notes: GAO analysis of VA data. Percentages may not add to 100 percent because of rounding.

After fiscal year 2000, overall funding for Gulf War illnesses research decreased. (See fig. 5.) Fiscal year 2003 research funding was about \$20 million less than funding provided in fiscal year 2000.

Figure 5: Funding for Gulf War Research Projects, Fiscal Years 1994-2003



Source: VA.

Note: GAO analysis of VA data. Only direct costs for each agency are included. Direct costs cover the actual research activities and materials and have not been adjusted for inflation.

This overall decrease in federal funding was paralleled by a shift in federal research priorities, which expanded to include all hazardous deployments and shifted away from a specific focus on Gulf War illnesses. VA officials said that although Gulf War illnesses research continues, the agency is expanding the scope of its research to include the potential long-term health effects in troops who served in hazardous deployments other than the Gulf War. In October 2002, VA announced plans to commit up to \$20 million for research into Gulf War illnesses and the health effects of other military deployments. Also in October 2002, VA issued a program announcement for research on the long-term health effects in veterans who served in the Gulf War or in other hazardous deployments, such as Afghanistan and Bosnia/Kosovo.⁵ As of April 2004, one new Gulf War illnesses research project was funded for \$450,000 under this program announcement.

⁵The October 2002 research program announcement on deployment health research remains open for researchers to submit proposals.

Although DOD has historically provided the majority of funding for Gulf War illnesses research, DOD officials stated that their agency currently has no plans to fund new Gulf War illnesses research projects. Correspondingly, DOD has not funded any new Gulf War illnesses research in fiscal year 2004, except as reflected in modest supplements to complete existing projects and a new award pending for research using funding from a specific appropriation. DOD also did not include Gulf War illnesses research funding in its budget proposals for fiscal years 2005 and 2006. DOD officials stated that because the agency is primarily focused on the needs of the active duty soldier, its interest in funding Gulf War illnesses research was highest when a large number of Gulf War veterans remained on active duty after the war—some of whom might develop unexplained symptoms and syndromes that could affect their active duty status.⁶ Since 2000, DOD's focus has shifted from research solely on Gulf War illnesses to research on medical issues of active duty troops in current or future military deployments.⁷ For example, in 2000 VA and DOD collaborated to develop the Millennium Cohort study, which is a prospective study evaluating the health of both deployed and nondeployed military personnel throughout their military careers and after leaving military service. The study began in October 2000 and was awarded \$5.25 million through fiscal year 2002, with another \$3 million in funding estimated for fiscal year 2003.

VA's Coordination of Federal Gulf War Illnesses Research Has Lapsed, and VA Has Not Determined Whether Key Research Questions Have Been Answered

VA's coordination of federal Gulf War illnesses research has gradually lapsed. Starting in 1993, VA carried out its responsibility for coordinating all Gulf War health-related activities, including research, through interagency committees, which evolved over time to reflect changing needs and priorities. (See fig. 1.) In 2000, interagency coordination of Gulf War illnesses research was subsumed under the broader effort of coordination for research on all hazardous deployments. Consequently, Gulf War illnesses research was no longer a primary focus. The most recent interagency research subcommittee, which is under the

⁶DOD officials also told us that there are about 100,000 Gulf War veterans currently on active military duty but these veterans generally are in good health.

⁷DOD refers to medical research related to current or future military deployments as its Force Health Protection Research Program. This program focuses on prevention of illness, reduction of injuries or the severity of injury, faster evacuation of casualties, and enhancements to general medical capabilities.

Deployment Health Working Group (DHWG), has not met since August 2003, and as of April 2004, no additional meetings had been planned.

Additionally, VA has not reassessed the extent to which the collective findings of completed Gulf War illnesses research projects have addressed the 21 key research questions developed by the RWG. (See app. II.) The only assessment of progress in answering these research questions was published in 2001, when findings from only about half of all funded Gulf War illnesses research were available. Moreover, the summary did not identify whether there were gaps in existing Gulf War illnesses research or promising areas for future research. No reassessment of these research questions has been undertaken to determine whether they remain valid, even though about 80 percent of federally funded Gulf War illnesses research projects now have been completed. In 2000, we reported that without such an assessment, many underlying questions about causes, course of development, and treatments for Gulf War illnesses may remain unanswered.⁸

DOD's Gulf War Investigations Are Complete

As of April 2003, DOD had completed all of its Gulf War health-related investigations, which are separate from Gulf War illnesses research. DOD began conducting investigations on Gulf War operations and their implications for service members' and veterans' health in 1996. Generally, DOD instituted an investigation after it received a report of a possible exposure to a chemical or biological agent or some other environmental, chemical, or biological hazard. From 1996 to 2003, DOD conducted 50 investigations at a cost of about \$68 million.

DOD published the 50 investigations in the form of 20 case narratives,⁹ 10 information papers,¹⁰ 5 closeout reports,¹¹ and 5 environmental exposure

⁸U.S. General Accounting Office, *Gulf War Illnesses: Management Actions Needed to Answer Basic Research Questions*, [GAO/NSIAD-00-32](#) (Washington D.C.: Jan. 6, 2000).

⁹Case narratives are interim reports of specific events that took place during the Gulf War and were updated pending further investigative efforts.

¹⁰Information papers are reports of what is known about military procedures and equipment used during the Gulf War.

¹¹A closeout report is used to close an investigation. The report is issued after an investigation has been reviewed and recommendations have been made to terminate the investigation.

reports.¹² Additionally, the RAND Corporation was contracted by the Office of Special Assistant for Gulf War Illnesses (OSAGWI) to publish 10 reports reviewing the medical and scientific literature on the known health effects of substances to which Gulf War veterans may have been exposed. Some investigations focused on examining possible exposures to chemical warfare agents or the presence of chemical weapons at specific sites. Other investigations studied the possible linkage between environmental hazards (such as contaminated water, equipment used during the Gulf War, oil well fires, and particulate matter) and illnesses or health effects.

OSAGWI published four annual reports summarizing the results of investigations. Generally, these reports concluded that there were limited exposures by troops to some hazards and limited or no short- or long-term adverse effects expected from these exposures. The last annual report was published in December 2000.

Some Efforts Are Under Way to Monitor Cancer Incidence among Gulf War Veterans, but Research Limitations May Impede Reliability of Results

As of April 2004, federal agencies had funded seven research projects related to cancer incidence among Gulf War veterans, four of which have been completed. Published results from the completed and ongoing studies generally show that rates of cancer among Gulf War veterans were similar to or lower than the rates among nondeployed veterans or the general population. However, results of these studies may not be reliable due to limitations in research related to cancer incidence in Gulf War veterans. Future research efforts may also be hindered by inadequate federal data on the health characteristics of Gulf War veterans.

¹²Environmental exposure reports are those that focus on exposure to potential environmental hazards.

Few Research Projects Related to Cancer Incidence in Gulf War Veterans Have Been Funded

Of the 240 federally funded research projects on Gulf War illnesses, VA officials stated that only 7 were related to cancer incidence in Gulf War veterans—accounting for about 3 percent of the entire research portfolio.¹³ Four of the seven research projects have been completed; the other three are ongoing. Only two of the seven research projects specifically studied cancer incidence. The remaining five research projects did not focus on cancer incidence, but instead included cancer as a component of a broader analysis of mortality, hospitalization, or general health status of Gulf War veterans. (See table 1 for more details on these studies.)

¹³Our review focused only on research related to cancer incidence among Gulf War veterans; therefore, Gulf War illnesses research projects studying other aspects of cancer, such as treatments for or causes of specific cancers, were not reviewed.

Table 1: Research Related to Cancer Incidence in Gulf War Veterans (GWV)

Description	Topic	Status	Published	Selected limitations
1 Postwar Hospitalization Experience of U.S. Veterans of the Persian Gulf War	Hospitalization	Complete	Yes ^a	Sample was limited to hospitalized GWV in VA, DOD, and some California hospitals. All other GWV were not included.
2 Combined Analysis of the VA and DOD Gulf War Clinical Registries	General health	Complete	Yes ^b	Sample was limited to GWV who self-enrolled in DOD and VA Gulf War clinical evaluation programs. All other GWV were not included.
3 National Health Survey of Persian Gulf Veterans	General health	Complete	Yes (interim) ^c	GWV self-reported data may be subject to overreporting of poor health status. Results were not supported by objective data or documentation.
4 Gulf War and Vietnam Veterans Cancer Incidence Surveillance	Cancer incidence	Complete	No	Due to the long latency period of cancer, ^e it may have been too early to study cancer incidence in GWV.
5 Deployment to the Gulf War and the Subsequent Development of Cancer	Cancer incidence	Ongoing	No	Due to the long latency period of cancer, ^e it may be too early to study cancer incidence in GWV.
6 Mortality Follow-up Study of Persian Gulf Veterans	Mortality	Ongoing	Yes (interim) ^d	Analysis only included GWV who have died of cancer. Other GWV who have not died, but have been diagnosed with cancer, were not included.
7 Longitudinal Health Study of Gulf War Veterans	General health	Ongoing	No	GWV self-reported data may be subject to overreporting of poor health status. Results may not be supported by objective data or documentation.

Sources: VA, DOD, and published manuscripts.

Note: GAO analysis of VA data, DOD data, and published manuscripts.

^aG. C. Gray and others, "The Postwar Hospitalization Experience of U.S. Veterans of the Persian Gulf War," *New England Journal of Medicine*, vol. 335, no. 20 (1996), 1505-13, and G. Gray and others, "Are Gulf War Veterans Suffering War-related Illnesses? Federal and Civilian Hospitalizations Examined, June 1991 to December 1994," *American Journal of Epidemiology*, vol. 151, no. 1 (2000), 63-71.

^bU.S. Department of Defense, *Combined Analysis of the VA and DOD Gulf War Clinical Evaluation Programs: A Study of the Clinical Findings from Systematic Medical Examinations of 100,339 U.S. Gulf War Veterans* (Washington, D.C.: 2002); T. C. Smith and others, "Ten Years and 100,000 Participants Later: Occupational and Other Factors Influencing Participation in U.S. Gulf War Health Registries," *Journal of Occupational and Environmental Medicine*, vol. 44, no. 8 (2002), 758-68; and T. C. Smith and others, "The Postwar Hospitalization Experience of Gulf War Veterans Participating in U.S. Health Registries," *Journal of Occupational and Environmental Medicine*, vol. 46, no. 4 (2004), 386-97.

^cH. K. Kang and others, "Illnesses Among United States Veterans of the Gulf War: A Population-Based Survey of 30,000 Veterans," *Journal of Occupational and Environmental Medicine*, vol. 42, no. 5 (2000), 491-501.

¹⁴H. K. Kang and T. A. Bullman, "Mortality among U.S. Veterans of the Persian Gulf War," *New England Journal of Medicine*, vol. 335, no. 20 (1996), 1498-504; H. K. Kang and T. A. Bullman, "Mortality Among U.S. Veterans of the Persian Gulf War: 7-Year Follow-Up," *American Journal of Epidemiology*, vol. 154, no. 5 (2001), 399-405; and U.S. Department of Veterans Affairs, *Mortality among U.S. Gulf War Veterans Who Were Potentially Exposed to Nerve Gas at Khamisiyah, Iraq* (Washington, D.C.: 2002).

¹⁵Some cancers can take 15 years or more to develop and be detected.

Overall, the four published research projects found that deployed Gulf War veterans did not have demonstrable differences in cancer-related ailments compared with nondeployed veterans or the general population. In addition, one of the published studies found that rates of hospitalization among Gulf War veterans were similar or lower than among nondeployed veterans, and another found that cancer-related mortality rates among Gulf War veterans were similar or lower than in the general population.

Research efforts are continuing for one of the two funded research projects specifically related to cancer incidence in Gulf War veterans. Researchers conducted a pilot project, scheduled to end in September 2004, which matched the cancer registries of six states and the District of Columbia¹⁴ with a database of all Gulf War veterans.¹⁵ In order to build on these efforts, the researchers plan to expand the pilot study to include additional states with cancer registries to obtain a more refined estimate of cancer incidence in Gulf War veterans. While this approach appears promising, the study's principal investigator said further efforts beyond September 2004 would be limited to working with state cancer registries that do not charge a fee or do not require on-site use of a registry.

Research Related to Cancer Incidence in Gulf War Veterans Has Several Limitations That Could Affect Reliability of Findings

A number of inherent limitations in research related to cancer incidence in Gulf War veterans could adversely affect the reliability of the findings from such research. (See table 1.) For example, since some cancers can take 15 years or more to develop and subsequently be detected, it may be too early to determine cancer incidence in Gulf War veterans, as studies 4 and 5 in table 1 were designed to do. Hospitalization studies of Gulf War veterans are applicable only to those veterans who seek care in specific hospitals

¹⁴The pilot study included cancer registries from California, Florida, Maryland, New Jersey, Texas, Virginia, and the District of Columbia.

¹⁵A cancer registry is an information system designed for the collection, management, and analysis of data on individuals with the diagnosis of a cancer, which may include data on the occurrence of cancer, the types of cancer that occur, the cancer's location in the body, the extent of disease at time of diagnosis, and the kinds of treatment patients receive.

included in the studies; veterans who use other health care systems are not included. Mortality studies of Gulf War veterans are limited because only veterans who have died of cancer are captured; other veterans who have not died, but have been diagnosed with cancer, are not included. Additionally, some general health studies of Gulf War veterans may use self-reported data only, which may not be accurate unless validated by objective physical or laboratory findings. Other research projects, which have samples that are not representative of all Gulf War veterans, such as studies 1 and 5 in table 1, may not reliably assess the possibility of elevated levels of cancer incidence or related ailments in Gulf War veterans when compared to the general population or nondeployed veterans.

Research related to cancer incidence in Gulf War veterans may also be hampered by incomplete federal data on the health characteristics of Gulf War veterans. In 1998, we reported that VA and DOD did not have data systems providing complete information on the health characteristics of Gulf War veterans that could be used to accurately estimate cancer incidence.¹⁶ For example, data from medical records and files on disability claims, treatment, and pensions do not include all Gulf War veterans. These data do not account for veterans who are separated from the services and receive non-VA health care or disability benefits. Furthermore, linking VA and DOD data systems still would not overcome these shortcomings. VA officials have also stated that existing data systems, such as medical record or pension systems, are not adequate for determining cancer incidence and that epidemiological research projects are needed.

¹⁶U.S. General Accounting Office, *Gulf War Veterans: Limitations of Available Data for Accurately Determining the Incidence of Tumors*, [GAO/T-NSIAD-98-186](#) (Washington D.C.: May 14, 1998) and *Gulf War Veterans: Incidence of Tumors Cannot Be Reliably Determined from Available Data*, [GAO/NSIAD-98-89](#) (Washington D.C.: Mar. 3, 1998).

RAC's Efforts to Provide Advice May Be Hindered by VA's Limited Information Sharing and Collaboration, but Several Changes to Address These Issues Have Been Proposed

RAC's efforts to provide advice and make recommendations on Gulf War illnesses research may have been impeded by VA's limited sharing of information on research initiatives and program planning as well as VA's limited collaboration with the committee. However, VA and RAC are exploring ways to improve information sharing, including VA's hiring of a senior scientist who would both guide the agency's Gulf War illnesses research and serve as the agency's liaison to provide routine updates to RAC. VA and RAC are also proposing changes to improve collaboration, including possible commitments from VA to seek input from RAC when developing research program announcements. At the time of our review, most of these proposed changes were in the planning stages.

RAC Officials Cite VA's Poor Information Sharing and Limited Collaboration as Impediments in Meeting Its Mission

According to RAC officials, VA senior administrators' poor information sharing and limited collaboration with the committee about Gulf War illnesses research initiatives and program planning may have hindered RAC's ability to achieve its mission of providing research advice to the Secretary of VA. RAC is required by its charter to provide advice and make recommendations to the Secretary of VA on proposed research studies, research plans, and research strategies relating to the health consequences of service during the Gulf War. (See app. III for RAC's charter.) RAC's chairman and scientific director said that the recommendations and reports that the advisory committee provides to the Secretary of VA are based on its review of research projects and published and unpublished research findings related to Gulf War illnesses.

Although RAC and VA established official channels of communication, VA did not always provide RAC with important information related to Gulf War illnesses research initiatives and program planning. In 2002, VA designated a liaison to work with RAC's liaison in order to facilitate the transfer of information to the advisory committee about the agency's Gulf War illnesses research strategies and studies. However, RAC officials stated that most communication occurred at their request; that is, the VA liaison and other VA staff were generally responsive to requests, but did not establish mechanisms to ensure that essential information about research program announcements or initiatives was automatically provided to the advisory committee. RAC officials cited the following instances in which VA did not fully collaborate with the advisory committee or provide information that RAC considered important:

-
- According to RAC's scientific director, bimonthly teleconferences between the advisory committee's and VA's liaisons did not result in full disclosure of relevant ongoing research activities. For example, despite several months of discussions in which RAC's liaison requested information about proposed research program announcements for Gulf War illnesses research, VA's liaison did not inform RAC that VA's Office of Research and Development was preparing a research program announcement until it was published in October 2002. Consequently, RAC officials said that they did not have an opportunity to carry out the committee's responsibility of providing advice and making recommendations on research strategies and plans.
 - RAC officials stated that VA did not notify advisory committee members that the Longitudinal Health Study of Gulf War Era Veterans—a study designed to address possible long-term health consequences of service in the Gulf War—had been developed and that the study's survey was about to be sent to study participants. RAC officials expressed concern that VA did not inform the advisory committee about the survey even after the plans for it were made available for public comment. Although the survey had been finalized, the study's principal investigator provided additional time to allow RAC to recommend additional survey question topics and incorporated RAC's suggested changes into the survey.
 - In May 2004, VA published its annual report that described the results, status, and priorities of federally funded Gulf War illnesses research as of 2002. However, RAC officials said they had not seen a draft of this report and had not been asked to review or comment on the document before it was published, even though the advisory committee has a responsibility to advise the Secretary of VA on the state and direction of Gulf War illnesses research.

According to RAC officials, there were also instances in which information relevant to Gulf War illnesses research provided by VA's liaison or other VA officials was unclear or incomplete. Miscommunication about the purpose of the October 2002 research program announcement and the details of a corresponding VA plan to increase funding up to \$20 million for research related to hazardous military deployments, which would include the Gulf War, led RAC members to believe that VA had committed a large portion of this \$20 million to Gulf War illnesses research for fiscal year 2004. Moreover, RAC officials did not receive routine reports on Gulf War illnesses research proposals that had been either received or funded by VA under the October 2002 research program announcement. RAC officials said that until VA administrators were asked to brief the advisory committee in February 2004, advisory committee members were unaware that only one new Gulf War illnesses research project had received

funding for fiscal year 2004 under this program announcement and that no other proposals were under review.

Information sharing about these types of issues is common practice among advisory committees of the National Institutes of Health (NIH), which has more federal advisory committees than any other executive branch agency.¹⁷ A senior official within NIH's Office of Federal Advisory Committee Policy said that it is standard practice for NIH advisory committees to participate closely in the development of research program announcements. For example, some advisory committees' members review preliminary drafts of announcements, and some discuss program announcements during regular committee meetings. Furthermore, this official stated that many NIH institutes require advisory committee approval before issuing research program announcements. In addition, NIH's advisory committee members are routinely asked to make recommendations on both research concepts and priorities for research projects, and are kept up-to-date about the course of ongoing research projects. This official also stated that NIH advisory committee members often review draft reports summarizing research findings or research progress prior to their publication.

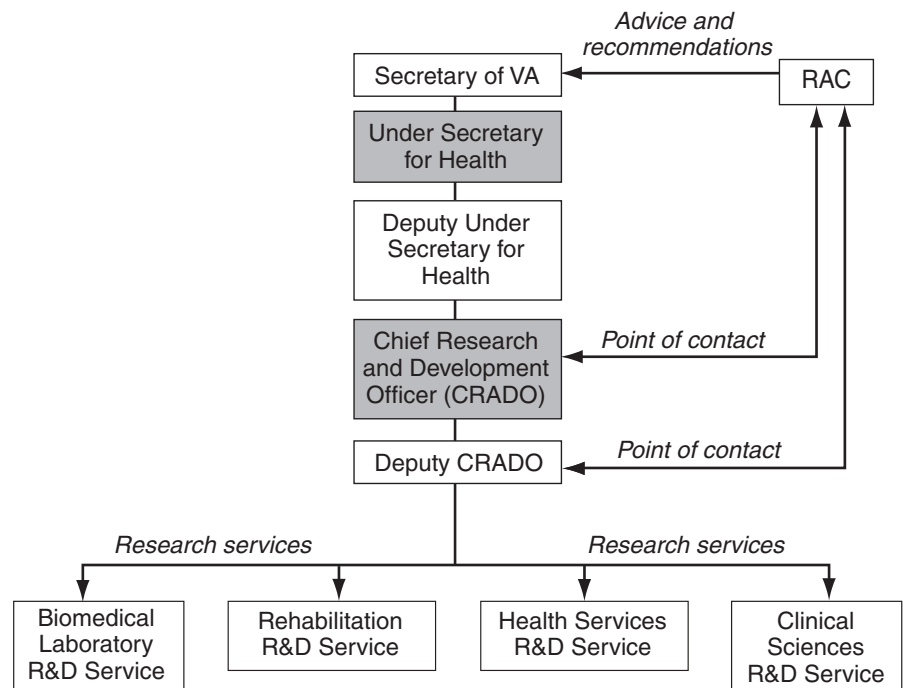
Additionally, RAC officials stated that VA's staffing choices for the liaison position and more recent VA staff turnover have hindered the development of working relationships and information flow. RAC officials stated that the initial VA liaison—a senior official in one of VA's four research services—was not very knowledgeable about current Gulf War illnesses research developments. In early 2003, VA's Chief Research and Development Officer (CRADO),¹⁸ whom RAC officials said was knowledgeable about Gulf War illnesses issues, began to serve as the VA liaison to RAC. (See fig. 6 for organizational chart.) However, this individual left VA in December 2003, and according to RAC officials, further communication with the advisory committee was delegated to lower-level VA staff. After the advisory committee's February 2004

¹⁷NIH is the largest funder of medical research in the United States and maintains more than 140 chartered advisory committees. NIH has four types of advisory committees—for the purposes of this report, we refer to practices of two committee types: program advisory committees and national advisory councils.

¹⁸The CRADO is responsible for oversight of research programs within the four VA research services: the Biomedical Laboratory Research and Development Service, the Clinical Science Research and Development Service, the Health Services Research and Development Service, and the Rehabilitation Research and Development Service.

meeting, the acting CRADO (appointed in December 2003) and the deputy CRADO began to communicate regularly with the advisory committee. However, the acting CRADO has additional management responsibilities that can limit the amount of time available to coordinate with RAC. Specifically, in early April 2004, this official was named to temporarily head VA's health care system—the Veterans Health Administration.¹⁹ For this reason, the deputy CRADO more often has acted as a point of contact for the committee.

Figure 6: Organizational Relationships between VA and RAC, as of April 2004



The same VA official was serving in each position as of April 2004.

Source: VA.

¹⁹The Veterans Health Administration is the nation's largest integrated health care system, employing more than 180,000 health care professionals and operating more than 1,300 health care facilities. In addition to its medical care mission, the veterans health care system is the nation's largest provider of graduate medical education and a major contributor to medical and scientific research.

VA and RAC Are Exploring Methods to Improve Information Sharing and Collaboration

In recognition of RAC's concerns, VA is proposing several actions to improve information sharing, including VA's hiring of a senior scientist to guide its Gulf War illnesses research and improving formal channels of communication. In addition, VA and RAC are exploring methods to improve collaboration. These would include possible commitments from VA to seek input from RAC when developing research program announcements and to include RAC members in a portion of the selection process for funding Gulf War illnesses research projects. As of April 2004, most of the proposed changes were in the planning stages.

Since the February 2004 RAC meeting, VA and RAC officials said they have had multiple meetings and phone conversations and have corresponded via e-mail in an attempt to improve communication and collaboration. VA officials said they have already instituted efforts to hire a senior scientist to guide the agency's Gulf War illnesses research efforts. The official assigned to this position will be the RAC liaison and coordinator of VA's research on Gulf War illnesses and health issues related to other hazardous deployments. According to VA officials, this official will be required to formally contact RAC officials weekly, with informal communications on an as needed basis. In addition, this official will be responsible for providing periodic information on the latest publications or projects related to Gulf War illnesses research.

To facilitate collaboration with RAC, VA has proposed involving RAC members in developing VA program announcements designed to solicit research proposals, both specifically for Gulf War illnesses and related areas of interest, such as general research into unexplained illnesses. RAC officials stated that throughout March and April 2004, VA and RAC officials had been jointly developing a new research program announcement for Gulf War illnesses. In addition, VA has proposed that RAC will be able to recommend scientists for inclusion in the scientific merit review panels. VA also plans to involve RAC in reviews of project relevancy to Gulf War illnesses research goals and priorities after the research projects undergo scientific merit review. This could facilitate RAC's ability to provide recommendations to the CRADO on the projects that it has judged to be relevant to the Gulf War illnesses research plan.

Conclusions

While more than 80 percent of federally funded Gulf War illnesses research projects have been completed, little effort has been made to assess progress in answering the 21 key research questions or to identify the direction of future research in this area. Additionally, in light of decreasing federal funds and expanding federal research priorities, research specific to Gulf War illnesses is waning. Without a comprehensive reassessment of Gulf War illnesses research, underlying questions about the unexplained illnesses suffered by Gulf War veterans may remain unanswered.

Since RAC's establishment in January 2002, its efforts to provide the Secretary of VA with advice and recommendations may have been hampered by incomplete disclosure of VA's Gulf War illnesses research activities. By limiting information sharing with RAC, VA has not fully realized the assistance that the scientists and veterans' advocates who serve on RAC could provide in developing effective policies and guidance for Gulf War illnesses research. VA and RAC are exploring new approaches to improve information sharing and collaboration. If these approaches are implemented, RAC's ability to play a pivotal role in helping VA reassess the direction of Gulf War illnesses research may be enhanced. However, most of these changes had not been formalized at the time of our review.

Recommendations for Executive Action

With respect to the federal Gulf War illnesses research efforts, we recommend that the Secretary of Veterans Affairs take the following action:

- conduct a reassessment of the Gulf War illnesses research strategy to determine whether the 21 key research questions have been answered, whether they remain relevant, and whether there are promising areas for future research.

To facilitate RAC's ability to provide advice on Gulf War illnesses research, we recommend that the Secretary of Veterans Affairs take the following additional two actions:

- ensure that a liaison who is knowledgeable about Gulf War illnesses research is appointed to routinely share information with RAC and
- ensure that VA's research offices collaborate with RAC on Gulf War illnesses research program development activities.

Agency Comments and Our Evaluation

We provided a draft of this report for comment to VA and DOD. In commenting on this draft, VA agreed with the report's conclusions and concurred with the report's recommendations. VA said that it has begun a preliminary assessment of the federal Gulf War illnesses research strategy, including an evaluation of the 21 key research questions, to ensure the research strategy's continued validity and to identify promising areas for future research. The agency also noted that it has undertaken various steps, such as coordinating its most recent request for Gulf War research applications with RAC, in order to better collaborate with the advisory committee. VA's written comments are in appendix IV.

DOD informed us that it had no substantive comments on the draft report. Both VA and DOD provided technical comments, which we incorporated where appropriate.

We are sending copies of this report to the Secretary of VA, the Secretary of Defense, and the Secretary of HHS. We will also provide copies to others upon request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please call me at (202) 512-7119 or Bonnie Anderson at (404) 679-1900. Karen Doran, John Oh, Danielle Organek, and Roseanne Price also made key contributions to this report.

Sincerely yours,



Janet Heinrich
Director, Health Care—Public Health Issues

Appendix I: Scope and Methodology

To describe the status of research and investigations on Gulf War illnesses, we reviewed reports to congressional committees outlining annually awarded and completed research projects and research funding. We summarized data from the Department of Veterans Affairs' (VA) annual reports to congressional committees, including numbers of funded research projects and total funding by federal agency, in order to determine the status of completed research. We interviewed VA's then-Assistant Chief Research and Development Officer (CRADO) and the Department of Defense's (DOD) Deputy Director of the Deployment Health Support Directorate (DHSD) regarding the agencies' current and future Gulf War illnesses research and investigation plans. We also interviewed CRADO and DHSD staff and senior managers with DOD's medical research offices, including Defense Research and Engineering and the Army's Medical Research and Materiel Command. We reviewed other relevant documents, including interagency coordinating council meeting minutes, federal laws, presidential directives, and VA- and DOD-published documents on Gulf War illnesses research and DOD investigations.

To describe efforts made by VA and DOD to monitor cancer incidence among Gulf War veterans, we interviewed VA's then-Assistant CRADO, a VA senior research manager, and VA researchers, along with DOD's Deputy Director of DHSD. We reviewed annual reports to congressional committees describing federally funded Gulf War illnesses research, published articles from peer-reviewed journals reporting research findings, and other agency documents describing research projects.

To evaluate the VA's Research Advisory Committee on Gulf War Veterans' Illnesses (RAC) efforts to provide advice on Gulf War illnesses research, we interviewed RAC's Chairman and Scientific Director, attended the most recent RAC meeting in February 2004, and reviewed RAC reports and recommendations to the Secretary of VA. We also interviewed officials with the National Institutes of Health's (NIH) Office of Federal Advisory Committee Policy and officials within an NIH advisory committee to identify common practices related to information sharing and collaboration between NIH and its advisory committees. To determine VA's efforts to improve information sharing and collaboration with RAC, we interviewed VA's deputy CRADO and CRADO staff.

Appendix II: Key Gulf War Illnesses Research Questions

From 1995 through 1996, the Research Working Group (RWG) of the interagency Persian Gulf Veterans' Coordinating Board identified 19 major research questions related to illnesses in Gulf War veterans. RWG later added 2 more questions to create a set of 21 key research questions to serve as a guide for federal research on Gulf War illnesses. (See table 3.)

Appendix II: Key Gulf War Illnesses Research Questions

Table 2: Twenty-one Key Gulf War Illnesses Research Questions

Research question number	Key research questions
1	What is the prevalence of symptoms/illnesses in the Persian Gulf veterans population? How does this prevalence compare to that in an appropriate control group?
2	What was the overall exposure of troops to <i>Leishmania tropica</i> ?
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 veterans' 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 Muhammadiyat and Al Muthannna, 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 pyridostigmine bromide use among Persian Gulf troops? ^a
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 nonspecific 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?
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 nonspecific 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 and 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?

Source: VA.

Appendix II: Key Gulf War Illnesses Research Questions

^aPyridostigmine bromide is a drug that was supplied to troops for use as a pretreatment for potential exposure to nerve agents.

Appendix III: Charter for VA's Research Advisory Committee on Gulf War Veterans' Illnesses

**DEPARTMENT OF VETERANS AFFAIRS
CHARTER OF THE
RESEARCH ADVISORY COMMITTEE ON
GULF WAR VETERANS' ILLNESSES**

A. OFFICIAL DESIGNATION: Research Advisory Committee on Gulf War Veterans' Illnesses (RACGWVI).

B. OBJECTIVES AND SCOPE OF ACTIVITY: The Department of Veterans Affairs (VA) Research Advisory Committee on Gulf War Veterans' Illnesses shall provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Persian Gulf War. The Committee shall not conduct scientific research.

The guiding principle for the work of the Committee shall be the premise that the fundamental goal of Gulf War-related government research, either basic or applied, is to ultimately improve the health of ill Gulf War veterans, and that the choice and success of research efforts shall be judged accordingly. The Committee shall assess the overall effectiveness of government research to answer central questions on the nature, causes, and treatments of Gulf War-associated illnesses.

The Committee shall review all relevant research, investigations, and processes for funding research conducted previously and assess their methods, results, and implications. The Committee shall review all proposed federal research plans, initiatives, procurements, grant programs, and other activities in support of research projects on Gulf War-associated illnesses. The Committee, consistent with law, shall have access to all VA documents and other sources of information it finds relevant to such review.

C. PERIOD OF TIME NECESSARY FOR THE COMMITTEE TO CARRY OUT ITS PURPOSE(S): The Committee was established in compliance with statutory instructions contained in Section 104 of Public Law 105-368. It has no termination date.

D. OFFICIAL TO WHOM THE COMMITTEE REPORTS: The Committee shall report to the Secretary of Veterans Affairs.

E. OFFICE RESPONSIBLE FOR PROVIDING THE NECESSARY SUPPORT TO THE COMMITTEE: The Department of Veterans Affairs will provide support for the Committee. A VA employee selected by the Secretary of Veterans Affairs shall be the Designated Federal Officer, under the direction of the Committee chair. Technical support for the Committee shall be provided by a staff that reports to the Committee chair, who may appoint a technical director for the staff to supervise its operation. Staff members may be VA employees, employees of other government agencies, or independent agents employed as temporary VA employees.

**Appendix III: Charter for VA's Research
Advisory Committee on Gulf War Veterans'
Illnesses**

F. DUTIES FOR WHICH THE COMMITTEE IS RESPONSIBLE: The Committee shall provide to the Secretary of Veterans Affairs, not later than December 1 of each year, an annual report summarizing its activities for the preceding year. The Committee is authorized to develop additional reports and recommendations regarding relevant research. During its review of such research and in compliance with governing law, the Committee shall have access to all VA documents and other information sources it finds relevant to such review. Recommendations contained within a formal Committee report shall be submitted to the Secretary and other appropriate officials, as directed by the Secretary.

To augment the expertise of the Committee, the Secretary may authorize the Committee to contract for the services of non-governmental consultants who may prepare reports and background papers or prepare other materials for consideration by the Committee, as appropriate.

The Committee shall be comprised of members of the general public, including Persian Gulf War veterans, representatives of such veterans, and members of the medical and scientific communities representing appropriate disciplines such as, but not limited to, biomedicine, epidemiology, immunology, environmental health, neurology, and toxicology. The Secretary of Veterans Affairs may appoint non-U.S. citizens as Committee members.

Members shall be appointed for two- or three-year terms. The Secretary may renew the terms of members. The Secretary shall appoint the chair of the Committee. The term of office for the chair shall be two years, also renewable by the Secretary.

The Committee may establish subcommittees to carry out specific projects or assignments. The Committee chair shall notify the Secretary upon the establishment of any subcommittee, including its function, members and estimated duration.

The Secretary may establish a panel of experts representing appropriate medical and scientific disciplines to assist the Committee in its work. Panelists may be called on by the Secretary for advice and consultation, and may advise the Committee on research or conduct other appropriate activities for the Committee, at the request of the Committee chair. Panelists shall report directly to the chair or such Committee members designated by the chair, but they shall not be members of the Committee. Panelists will be nominated by the Committee chair and appointed by the Secretary.

G. ESTIMATED ANNUAL OPERATING COSTS IN DOLLARS AND STAFF-YEARS: The estimated annual cost for operating the Committee and its support staff is \$400,000 and 4 FTE. All members will receive travel expenses and a per diem allowance in accordance with the Federal Travel Regulations for any travel made in connection with their duties as members of the Committee.

H. ESTIMATED NUMBER AND FREQUENCY OF MEETINGS: Meetings of the Committee shall occur not less than twice annually at the call of the chair. Meetings of the subcommittee(s) shall be convened as necessary. A federal government official shall be present at all meetings.

**Appendix III: Charter for VA's Research
Advisory Committee on Gulf War Veterans'
Illnesses**

I. COMMITTEE TERMINATION DATE: None.

J. DATE CHARTER IS FILED:

APPROVED:	-- Signed --	4/19/04
	Secretary of Veterans Affairs	Date

Source: RAC.

Appendix IV: Comments from the Department of Veterans Affairs



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

May 26, 2004

Ms. Janet Heinrich
Director, Health Care Team
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Heinrich:

The Department of Veterans Affairs (VA) has reviewed your draft report, **DEPARTMENT OF VETERANS AFFAIRS: Federal Gulf War Illnesses Research Strategy Needs Reassessment** (GAO-04-767) and agrees with your conclusions and concurs with your recommendations.

VA has already begun its assessment of the existing Federal Gulf War veterans' illnesses research strategy to ensure its continued validity and to identify promising areas for future research. Each of the 21 research questions will be thoroughly evaluated to determine which ones have been answered and require additional study and what new questions should be added.

To date, reviews of four questions have been done. Once the initial assessment is completed, VA will present it to the Research Advisory Committee (RAC) and to the Research Subcommittee of the Deployment Health Working Group for their comment.

VA has also taken numerous steps to ensure that an effective relationship exists with the RAC. The Acting Under Secretary for Health and the Deputy Chief Research and Development Officer regularly communicate with the RAC Chairman. Since February 2004, VA has had a designated liaison to the RAC scientific officer. However, since the Department's liaison also has other duties, VA hopes soon to recruit a full-time health scientist to serve as liaison and as portfolio manager for Gulf War and deployment health studies.

In addition, VA coordinated its most recent Gulf War request for application with the committee and will do the same with the planned Gulf War veterans' illnesses request for proposal for autumn 2004. The RAC provided valuable recommendations, and while our coordination efforts may not have been seamless, we believe that they have improved significantly over the past 2 years.

The Department's GAO Liaison passed several technical corrections to GAO separately. VA appreciates the opportunity to comment on your draft report.

Sincerely yours,

A handwritten signature in black ink that reads "Anthony J. Principi".

Anthony J. Principi

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