

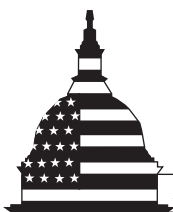


Report to the Ranking Member,
Subcommittee on Health, Committee
on Veterans' Affairs, House of
Representatives

January 2011

VA HEALTH CARE

VA Spends Millions on Post-Traumatic Stress Disorder Research and Incorporates Research Outcomes into Guidelines and Policy for Post- Traumatic Stress Disorder Services



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Why GAO Did This Study

In addition to providing health care to veterans, the Department of Veterans Affairs (VA) funds research that focuses on health conditions veterans may experience. According to VA, experts estimate that up to 20 percent of Operation Enduring Freedom and Operation Iraqi Freedom veterans have experienced post-traumatic stress disorder (PTSD) and demand for PTSD treatment is increasing. Because of the importance of research in improving the services that veterans receive, GAO was asked to report on VA's funding of PTSD research, and its processes for funding PTSD research proposals, reviewing and incorporating research outcomes into clinical practice guidelines (CPG)—tools that offer clinicians recommendations for clinical services but do not require clinicians to provide one service over another—and determining which PTSD services are required to be made available at VA facilities. To do this work, GAO obtained and summarized VA data on the funding of PTSD research from its medical and prosthetic research appropriation through its intramural research program. GAO also reviewed relevant VA documents, such as those for developing CPGs and those related to VA's 2008 *Uniform Mental Health Services in VA Medical Centers and Clinics* handbook (Handbook), which defines certain mental health services that must be made available at VA facilities. GAO also interviewed VA officials.

View [GAO-11-32](#) or key components. For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

January 2011

VA HEALTH CARE

VA Spends Millions on Post-Traumatic Stress Disorder Research and Incorporates Research Outcomes into Guidelines and Policy for Post-Traumatic Stress Disorder Services

What GAO Found

Based on VA data GAO obtained and summarized, GAO found that the amount of funding VA provided for intramural PTSD research increased from \$9.9 million in fiscal year 2005 to \$24.5 million in fiscal year 2009. From fiscal year 2005 through fiscal year 2009, intramural PTSD research funding ranged from 2.5 percent to 4.8 percent of VA's medical and prosthetic research appropriation. In addition, the number of PTSD research studies VA funded through the Merit Review Program and the Cooperative Studies Program (CSP)—VA's two primary funding mechanisms in its intramural research program—increased from 47 in fiscal year 2005 to 96 in fiscal year 2009.

According to VA officials, intramural research proposals, including those on PTSD, are funded primarily according to scientific merit in both the Merit Review Program and CSP. Proposals are evaluated by a panel of reviewers and scored based on their scientific merit. Directors of VA's research and development services—offices that focus on different research areas and administer VA's intramural research program—fund proposals based on their scores, typically up to a specified percentile. The number of proposals funded may vary based on budgetary considerations and, for a small number of proposals, responsiveness to VA research priority areas.

VA has a process to review and incorporate relevant research outcomes to develop CPGs for a number of topics, including PTSD. VA relies on the policies of a joint VA and Department of Defense (DOD) work group—comprised of VA and DOD officials—to ensure that systematic reviews of relevant research outcomes are conducted when issuing CPGs. In brief, a systematic review is conducted to identify the most methodologically rigorous research studies that are applicable to each clinical question contained in the CPG. A group of subject matter experts then assesses the individual research studies in order to determine the overall quality of evidence available for each particular clinical question, considers the potential benefits and harms of a clinical intervention to determine its net effect, and, based on an assessment of the overall quality of the evidence and the net effect of an intervention, develops recommendations for the CPG.

According to VA officials, the decision to require that two PTSD services—cognitive processing therapy and prolonged exposure therapy—be made available at VA facilities by including them in the Handbook was based on a review of research outcomes and the availability of existing resources. Specifically, VA officials told GAO that these two services were strongly recommended in the 2004 PTSD CPG and had greater evidence supporting their effectiveness than other PTSD services. VA also told GAO that prior to the Handbook's 2008 issuance, VA had already begun investing resources in training programs for cognitive processing therapy in 2006 and prolonged exposure therapy in 2007. While VA provided some documentation regarding the decision-making process for PTSD services, VA officials explained that clinical decision-making processes are not typically expected to be documented in a formal manner. VA officials told GAO that they are currently clarifying language in the Handbook but do not plan to revise any requirements relating to PTSD services at this time.

VA provided technical comments that GAO incorporated as appropriate.

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Abbreviations

CPG	clinical practice guideline
CSP	Cooperative Studies Program
DOD	Department of Defense
Handbook	<i>Uniform Mental Health Services in VA Medical Centers and Clinics</i> handbook
ORD	Office of Research and Development
PTSD	post-traumatic stress disorder
VA	Department of Veterans Affairs

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United States Government Accountability Office
Washington, DC 20548

January 24, 2011

The Honorable Michael H. Michaud
Ranking Member
Subcommittee on Health
Committee on Veterans' Affairs
House of Representatives

Dear Mr. Michaud:

In addition to providing health care to about 5 million veterans each year, the Department of Veterans Affairs (VA) also funds research that focuses on the specific health conditions that veterans may experience. One condition that is examined in VA-funded research is post-traumatic stress disorder (PTSD), an anxiety disorder that can occur after a person is exposed to a life-threatening event.¹ Veterans diagnosed with PTSD may experience problems sleeping, maintaining relationships, and returning to their previous civilian lives.² According to VA, experts estimate that up to 20 percent of Operation Enduring Freedom and Operation Iraqi Freedom veterans,³ up to 10 percent of Gulf War veterans, and up to 30 percent of Vietnam War veterans have experienced PTSD.⁴ Consequently, demand for PTSD treatment continues to grow. VA data show that from fiscal year 2004 through fiscal year 2008, the number of unique veterans receiving treatment for PTSD increased by 60 percent from over 274,000 to over 442,000. In particular, the number of Operation Iraqi Freedom and Operation Enduring Freedom veterans who received VA treatment for

¹American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (Washington, D.C., 2000).

²Those diagnosed with PTSD may also suffer from other ailments, such as depression and substance abuse.

³Operation Enduring Freedom, which began in October 2001, supports combat operations in Afghanistan and other locations, and Operation Iraqi Freedom, which began in March 2003, supports combat operations in Iraq and other locations. In September 2010, Operation Iraqi Freedom became known as Operation New Dawn.

⁴Estimates for veterans who have experienced PTSD vary. For example, according to VA, regarding Operation Enduring Freedom and Operation Iraqi Freedom veterans, one 2008 RAND study found that approximately 14 percent of these veterans have experienced PTSD, while another 2004 study by Hoge *et al.* estimated that from 6 to 20 percent of those veterans have experienced PTSD.

PTSD increased from nearly 4,400 in fiscal year 2004 to over 69,000 in fiscal year 2008.

Veterans diagnosed with PTSD can receive a range of treatments to manage their symptoms, including individual and group therapy and medication. Veterans can receive PTSD treatment on an outpatient basis at VA facilities such as medical centers, community-based outpatient clinics, and Vet Centers.⁵ Veterans can also receive intensive treatment through VA medical center inpatient settings for acute care needs and through residential rehabilitation treatment programs for more prolonged rehabilitative care.

VA has guidance and policies in place related to PTSD services. For example, in 2004, the joint VA/Department of Defense (DOD) Evidence-Based Practice Work Group⁶ issued a CPG for PTSD.⁷ The PTSD CPG is an educational tool for clinicians that provides evidence-based recommendations⁸ for PTSD services based on a review of PTSD research outcomes. It does not require clinicians to provide one service over another. However, in a handbook issued in 2008—*Uniform Mental Health Services in VA Medical Centers and Clinics* (Handbook)—VA for the first time required certain mental health services to be made available to

⁵Vet Centers offer readjustment counseling—a wide range of psychosocial services that includes individual and group counseling and screening and referrals for medical issues—to eligible veterans and their families.

⁶Formed in 1999 and composed of VA and DOD officials, the VA/DOD Evidence-Based Practice Work Group makes decisions about which clinical practice guidelines (CPG) for specific conditions will be developed and oversees their development. As of August 2010, the VA/DOD Evidence-Based Practice Work Group had issued 24 CPGs on conditions such as chronic heart failure and major depressive disorder. Since VA and DOD issue the CPGs in a joint effort, they are intended to be used by both VA and DOD clinicians. The VA/DOD Evidence-Based Practice Work Group is supported by VA's Office of Quality and Performance and the U.S. Army Medical Department's Office of Quality Management.

⁷The PTSD CPG is formally known as the *VA/DOD Clinical Practice Guideline for the Management of Post-Traumatic Stress* (January 2004).

⁸Evidence-based care refers to approaches that have consistently been shown in controlled research to be effective for a particular condition or conditions.

veterans throughout the system.⁹ For PTSD, the Handbook requires that cognitive processing therapy or prolonged exposure therapy, two evidence-based psychotherapies, be provided or made available at VA facilities.¹⁰

Through its intramural research program, VA funds studies on different topics, such as PTSD. VA intramural studies are conducted by VA investigators—that is, researchers who conduct VA research studies. VA intramural research refers to research that is funded by and conducted within VA. In fiscal year 2009, VA received an appropriation of \$510 million for medical and prosthetic research.¹¹ This appropriation funds VA’s intramural research program, including providing funding for necessary equipment and supplies.¹² VA also receives three medical care appropriations that support VA’s intramural research by paying some of the costs associated with this research, for example, the salaries of VA

⁹Veterans Health Administration Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics* (Sept. 11, 2008). According to the Handbook, all veterans with PTSD must have access to cognitive processing therapy or prolonged exposure therapy. VA medical centers and very large community-based outpatient clinics (serving more than 10,000 unique veterans each year) must be able to provide staff to administer such services at the facilities. Large (serving 5,000 to 10,000 unique veterans each year) and midsized (serving 1,500 to 5,000 unique veterans each year) community-based outpatient clinics may provide these services through telemental health or contract care when necessary. In March 2010, VA issued the Veterans Health Administration Handbook 1160.03, *Programs for Veterans with Post-Traumatic Stress Disorder (PTSD)*, to provide additional information regarding the implementation of the PTSD requirements contained in the 2008 Handbook.

¹⁰Psychotherapies focus on changing individuals’ behaviors, thoughts, perceptions, and emotions. Cognitive processing therapy utilizes trauma-specific cognitive techniques to help patients move past trauma-related thoughts and progress toward recovery. Prolonged exposure therapy works by helping individuals approach trauma-related thoughts, feelings, and situations that they have been avoiding because of the distress they cause. Repeated exposure to these thoughts, feelings, and situations can assist with reducing the likelihood they will cause distress.

¹¹VA’s medical and prosthetic research appropriation pays for necessary expenses in carrying out programs of medical and prosthetic research and development as authorized by chapter 73 of title 38, United States Code, the authorizing laws for the Veterans Health Administration. See Pub. L. No. 110-329, 122 Stat. 3574, 3706 (2008).

¹²The medical and prosthetic research appropriation funds research on different topics. It is not limited to funding research on PTSD.

investigators who are also VA clinicians.¹³ According to VA, in fiscal year 2009, VA's medical care appropriations totaled about \$41 billion and VA provided \$433 million of that amount to support all research conducted at VA facilities.¹⁴

Because of the growing demand for PTSD services and the importance of research in improving the health care services that veterans receive, you asked us to report on VA's funding of PTSD research, VA's processes for reviewing PTSD research proposals, VA's incorporation of research outcomes into clinical practice, and VA's process for determining which PTSD services it requires VA facilities to provide or make available. This report will describe

- how much funding VA provided for intramural PTSD research from its medical and prosthetic research appropriations from fiscal year 2005 through fiscal year 2009,
- how VA determines which intramural PTSD research studies will be funded,
- how VA reviews PTSD research outcomes and incorporates them into its PTSD CPG, and
- how VA determines which PTSD services it requires VA facilities to provide or make available.

To describe how much funding VA provided for PTSD research from its medical and prosthetic research appropriations through its intramural research program from fiscal year 2005 through fiscal year 2009, we obtained and summarized data provided by VA's Office of Research and

¹³VA's three medical care appropriations are (1) medical services, which provides funds for the provision of veterans' health care services; (2) medical support and compliance, which provides funds for expenses related to the administration of veterans' health care services; and (3) medical facilities, which provides funds for the operation and maintenance of VA's health care facilities. Each of these appropriations provides support to all research conducted at VA facilities. For example, the medical care appropriations pay for the salaries of VA investigators who are VA clinicians (according to VA, about 70 percent of VA investigators are VA clinicians), administrative costs such as those for payroll and human resources, and logistical and infrastructure costs.

¹⁴VA could not provide an estimate for the amount of funding VA spent from the medical care appropriations for intramural PTSD research. Of the \$433 million, more than half went to personnel costs, including the salaries of clinicians and other VA facility staff.

Development (ORD), the office that manages the Merit Review Program and the Cooperative Studies Program (CSP)—the two primary funding mechanisms within VA’s intramural research program.¹⁵ VA officials define PTSD research as “the effort to acquire generalizable knowledge about causes, epidemiology, susceptibility and genetics, resilience, pathophysiology, prevention and treatment of post-traumatic stress disorder.” Based on these data, for fiscal years 2005 through 2009, we calculated totals and trends for (1) overall intramural PTSD research funding—including PTSD research studies and other PTSD research-related funding, such as career development awards provided to junior VA investigators to conduct PTSD studies, salaries for VA investigators who are not VA clinicians,¹⁶ funding for PTSD research conducted within ORD research centers, and PTSD research meetings, and (2) the number and type of intramural PTSD research studies funded. According to VA, the funding data we obtained from VA do not include funds provided to conduct or support intramural PTSD research from VA’s medical care appropriations.¹⁷ Because of this, they do not necessarily represent all the funding VA provided for PTSD research during this time. In addition, to obtain information about how VA funds research conducted at VA, we interviewed officials from VA’s Veterans Health Administration’s Office of Finance, ORD, and Veterans Integrated Service Networks.¹⁸ We also reviewed VA documents regarding its total medical and prosthetic research appropriations. We tested the internal consistency and reliability of the PTSD research data by reviewing the data for obvious outliers and

¹⁵The data provided by ORD reflect the funding amounts VA investigators were authorized to use, not necessarily the amounts that were spent. VA officials said that the authorized amounts are very similar to the amounts that are spent.

¹⁶Salaries for VA investigators who are VA clinicians are paid from the medical services appropriation, one of the medical care appropriations.

¹⁷For example, VA’s Veterans Integrated Service Networks, which receive funding from the medical care appropriations and include VA’s medical facilities, may also fund research by VA investigators, but this research funding is not considered part of VA’s intramural research program. According to ORD officials, about 95 percent of the PTSD research funded by VA is funded by VA’s intramural research program.

¹⁸The management of VA’s medical facilities is decentralized to 21 regional networks referred to as Veterans Integrated Service Networks.

performing consistency checks. We found the data to be sufficiently reliable for the purposes of this report.¹⁹

To describe how VA determines which intramural PTSD research studies will be funded, we interviewed VA officials responsible for managing VA's intramural research program. We also obtained and analyzed VA documents that describe VA's policies for submitting, reviewing, and funding intramural research proposals. In addition, to understand the process VA uses to evaluate intramural research proposals, we observed a meeting in which research proposals were evaluated.

To describe how VA reviews PTSD research outcomes and incorporates them into its PTSD CPG to inform clinical practice at VA, we interviewed VA officials who are responsible for developing CPGs. We also obtained and reviewed the PTSD CPG and documents related to CPG development.

To describe how VA determines which PTSD services it requires VA facilities to provide or make available to veterans, we interviewed VA officials responsible for determining these requirements. We also obtained and reviewed documents that describe the PTSD service requirements.

We conducted this performance audit from May 2010 through November 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹⁹In 2010, the VA Office of Inspector General found issues with ORD's validation of some research expenditure data reported by investigators at the VA Maryland Health Care System facility. See Department of Veterans Affairs, Office of Inspector General, *Health Care Inspection: Inappropriate Research and Development Data Entries Affecting Veterans Equitable Research Allocation (VERA) Funding VA Maryland Health Care System Baltimore, MD* (Washington, D.C., Sept. 23, 2010). According to VA officials, the PTSD research funding data we obtained for this report were generated from a different data system than the data systems specifically examined by the VA Office of Inspector General. In addition, the PTSD research funding data are entered by VA officials at the central office and checked for accuracy by VA officials at both the central office and the facilities.

Background

VA manages its intramural research program through ORD. According to ORD's 2009 to 2014 strategic plan, ORD has 10 research priority areas, which are topics of research that are considered important to VA.²⁰ The research priority areas are the health care needs of veterans who have served in Operation Enduring Freedom and Operation Iraqi Freedom, aging-related conditions, mental health care and well-being, chronic diseases, long-term care and caregiving, deployment-related exposure to hazardous environmental agents, equity in care, access in rural areas, women's health, and personalized medicine. According to VA officials, all of these research priority areas could include PTSD research.

VA funds intramural research through the following:

- VA's Merit Review Program: This program supports research studies typically conducted by one VA investigator at one VA facility and is administered by ORD's four research and development services, each of which has a different research focus. (See table 1.) Each research and development service is responsible for soliciting, reviewing, selecting, and funding research proposals submitted to the service.

Table 1: The Office of Research and Development's Research and Development Services

Research and development service	Focus of research	Examples of research
Biomedical Laboratory	Biological or physiological principles in humans or animals	Investigations of tissues, blood, or other biologic specimens
Clinical Science	Human beings	Clinical studies examining interventions and effectiveness; epidemiological studies
Health Services	The interface of health care systems, patients, and health care outcomes	Studies examining quality, access, patient outcomes, and costs
Rehabilitation	Improving the quality of life of impaired and disabled veterans	Veteran rehabilitation studies; studies focused on identifying technical solutions for impaired and disabled veterans

Source: GAO analysis of Department of Veterans Affairs information.

²⁰In 2009, VA's Office of Inspector General found that appropriated funds for VA research addressed the broad spectrum of medical issues with which veterans contend. See Department of Veterans Affairs, Office of Inspector General, *Healthcare Inspection: Review of the Veterans Health Administration's Use of Appropriated Funds for Research* (Washington, D.C., 2009).

- VA's CSP: This program, which is administered by Clinical Science, funds larger-scale, multisite clinical trials and epidemiological research studies on key diseases that impact veterans.

The Merit Review Program has research award funding limits, which are set by VA. In some cases, intramural research awards may only be funded for a certain number of years. See table 2 for more information.

Table 2: Department of Veterans Affairs (VA) Intramural Research Study Funding Limits and Maximum Length of Award by Research and Development Service

Service	Funding limit per award per fiscal year		Maximum length of award (in fiscal years)	
	Pilot study ^a	Full study	Pilot study ^a	Full study
Biomedical Laboratory	N/A	\$150,000 ^b	N/A	4
Clinical Science	N/A	\$150,000 ^b	N/A	4 (5 for clinical trials)
Cooperative Studies Program	N/A	No limit	N/A	No limit
Health Services	\$100,000	\$300,000 ^c	1	4
Rehabilitation	\$75,000	\$300,000	2	4

Source: GAO analysis of VA information.

^aA pilot study is a study to establish feasibility or to develop data, a technique, a concept, or a procedure, which is preliminary to undertaking a full study. Two of VA's Office of Research and Development's research and development services—Health Services and Rehabilitation—accept pilot study proposals in addition to full study proposals.

^bAccording to VA officials, this limit may be exceeded for funding the salaries of investigators who are not VA clinicians or for equipment.

^cAccording to VA officials, the total over all years may not exceed \$925,000.

In addition to individual studies conducted at VA facilities, VA has several research centers and programs that conduct or support PTSD research. For example, the National Center for PTSD focuses on PTSD research. VA also has Research Enhancement Award Programs, which help support PTSD research by providing staff and other resources to investigators. (For more information on VA research centers and research programs that conduct or support PTSD research, see app. I.) According to a VA official from the National Center for PTSD, VA does not fund most of the PTSD research that is being conducted today.

Origin and Criteria for Intramural Research Proposals

Intramural research proposals may be service-directed—solicited by ORD on specific topics—or investigator-initiated—submitted by investigators to ORD on their own initiative. Investigators submit proposals either in response to a request for proposals on a specific topic (for service-

directed proposals) or to an open request for proposals (for investigator-initiated proposals). For both the Merit Review Program and CSP, proposals are typically evaluated in two review cycles per year.²¹

To be considered for intramural research funding:²²

- The proposal must be veteran-centric.
- The proposal must have received approval from the director of the medical center and the research and development office of the medical center where the lead investigator, known as a principal investigator, is based.²³
- The principal investigator and any coprincipal investigators must demonstrate a primary professional commitment to VA, as demonstrated by at least a 5/8 time VA appointment at the time the funding is awarded and previous VA experience, including experience in research and patient care.²⁴
- Research must be conducted primarily on VA premises. The principal investigator and any coprincipal investigators must have designated research space within a VA medical center.²⁵

²¹According to VA, proposals may be reviewed outside of a review cycle depending on when ORD solicits requests for proposals. In rare cases, service-directed proposals are reviewed by ad hoc reviewers or solely by research and development service directors.

²²Each research and development service may have additional requirements.

²³The approval indicates that the medical center has agreed to commit the resources, such as space and staff, necessary to conduct the research study.

²⁴Investigators who do not demonstrate a primary professional commitment to VA can request a waiver of this requirement. According to a VA document, a waiver may be granted by VA officials depending on the circumstances of the request, such as for a retired investigator who previously received funding through the Merit Review Program. According to VA, waivers are granted for about 35 investigators per year.

²⁵The principal investigator and any coprincipal investigators may also have a designated research space in an approved non-VA facility or other VA facility, such as a community-based outpatient clinic.

PTSD Research Funding Increased from Fiscal Year 2005 through Fiscal Year 2009

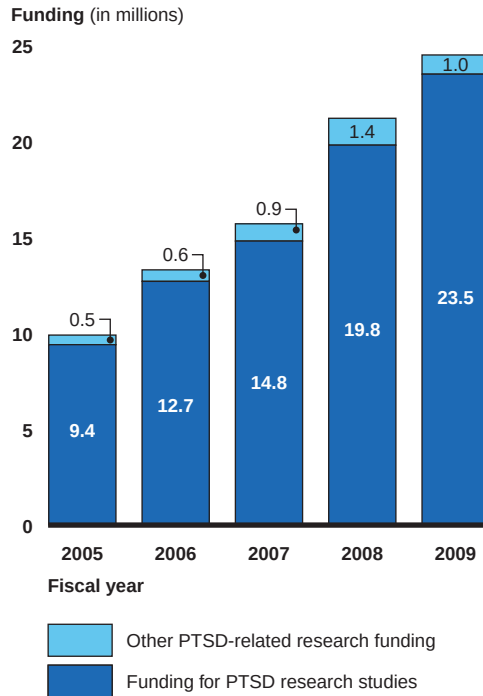
Overall intramural PTSD research funding from VA's medical and prosthetic research appropriation increased from \$9.9 million in fiscal year 2005 to \$24.5 million in fiscal year 2009. The number of intramural PTSD research studies funded through the Merit Review Program and CSP increased from 47 in fiscal year 2005 to 96 in fiscal year 2009.

VA Intramural PTSD Research Funding Increased from \$9.9 Million in Fiscal Year 2005 to \$24.5 Million in Fiscal Year 2009

Based on the VA data we obtained and summarized, we found that overall intramural PTSD research funding from VA's medical and prosthetic research appropriation increased from about \$9.9 million in fiscal year 2005 to about \$24.5 million in fiscal year 2009, or by about 150 percent (see fig. 1). Overall intramural PTSD research funding included funding for specific PTSD studies as well as for other PTSD research-related funding, such as career development awards provided to junior VA investigators to conduct PTSD studies, salaries for VA investigators who are not VA clinicians,²⁶ funding for PTSD research conducted within ORD research centers, and PTSD research meetings.

²⁶Salaries for VA investigators who are VA clinicians are paid from the medical services appropriation, one of the medical care appropriations.

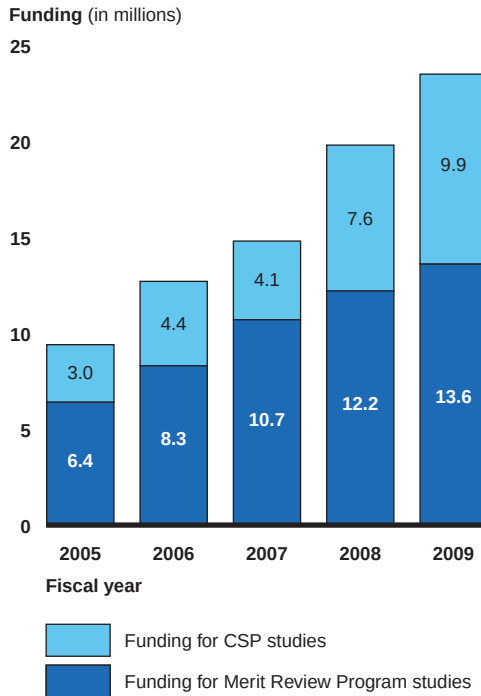
Figure 1: Department of Veterans Affairs (VA) Intramural Funding for Post-Traumatic Stress Disorder (PTSD) Research Studies and Other PTSD Research-Related Funding, Fiscal Years 2005 through 2009



Source: GAO analysis of VA data.

Of the \$80.2 million provided for PTSD studies from fiscal year 2005 through fiscal year 2009, \$51.3 million, or about 64 percent, was for studies funded through the Merit Review Program. The remaining approximately \$28.9 million, or about 36 percent, was for CSP studies. (See fig. 2.)

Figure 2: Department of Veterans Affairs (VA) Intramural Post-Traumatic Stress Disorder (PTSD) Funding for Merit Review Program Studies and Cooperative Studies Program (CSP) Studies, Fiscal Years 2005 through 2009



Source: GAO analysis of VA data.

From fiscal year 2005 through fiscal year 2009, intramural PTSD research funding ranged from 2.5 percent to 4.8 percent of VA's medical and prosthetic research appropriation. (See table 3 for VA intramural PTSD research funding and VA's medical and prosthetic research appropriations from fiscal year 2005 through fiscal year 2009.) For comparison,²⁷ according to a 2009 report prepared by ORD staff for VA's National Research Advisory Council,²⁸ for fiscal year 2009, funding for intramural traumatic brain injury research was about \$14.6 million, 2.9 percent of the medical and prosthetic research appropriation. Funding for spinal cord

²⁷Because of potential overlap in research areas, percentage estimates should not be added.

²⁸The National Research Advisory Council is responsible for advising the Secretary of Veterans Affairs and the Under Secretary for Health on matters related to VA's research. The Office of Management and Budget requires that the National Research Advisory Council conduct an annual assessment of VA's intramural research program.

injury research was \$27.2 million, 5.3 percent of the medical and prosthetic research appropriation. Funding for intramural cardiovascular disease and stroke research was \$53.1 million, 10.4 percent of the medical and prosthetic research appropriation.

Table 3: Department of Veterans Affairs (VA) Intramural Post-Traumatic Stress Disorder (PTSD) Research Funding and VA's Medical and Prosthetic Research Appropriation, Fiscal Years 2005 through 2009

Dollars in millions			
Fiscal year	VA intramural PTSD research funding	VA's medical and prosthetic research appropriation	Percentage
2005	\$9.9	\$390.2	2.5
2006	13.3	412.0	3.2
2007	15.7	446.5	3.5
2008	21.3	480.0	4.4
2009	24.5	510.0	4.8
Total	\$84.7	\$2,238.7	3.8

Source: GAO analysis of VA data.

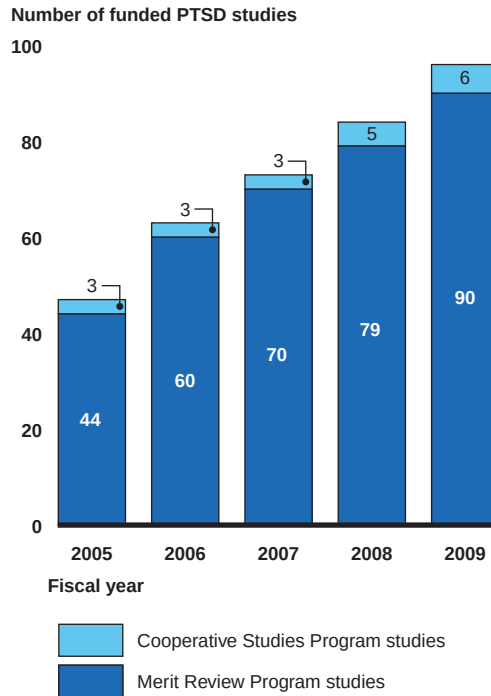
Note: VA intramural research is also supported by VA's medical care appropriations, which are not represented in this table. For example, the medical care appropriations pay for the salaries of VA investigators who are VA clinicians (according to VA, about 70 percent of VA investigators are VA clinicians), administrative costs such as payroll and human resources, and logistical and infrastructure costs.

The Number of PTSD Studies Funded through VA's Intramural Research Program Increased from 47 in Fiscal Year 2005 to 96 in Fiscal Year 2009

Similarly, we found that the number of PTSD studies funded from VA's medical and prosthetic research appropriations through VA's intramural research program increased from fiscal year 2005 through fiscal year 2009. (See fig. 3.) Specifically, in fiscal year 2005, 47 intramural PTSD research studies were funded while in fiscal year 2009, 96 intramural PTSD research studies were funded.²⁹ This represented an increase of more than 100 percent. Of all the studies funded each fiscal year, only a small number were CSP studies.

²⁹VA intramural research studies may be funded for multiple years (see table 2). Therefore, the same intramural PTSD research study funded in one fiscal year may also be funded the following fiscal year. In our analysis, this study would be counted as a funded study each fiscal year. In addition, some studies were not funded each fiscal year of their duration. For example, a study that was conducted from fiscal year 2006 through fiscal year 2009 may not have received funding in fiscal year 2007.

Figure 3: Number of Department of Veterans Affairs (VA) Intramural Post-Traumatic Stress Disorder (PTSD) Research Studies Funded per Fiscal Year, Fiscal Years 2005 through 2009



Source: GAO analysis of VA data.

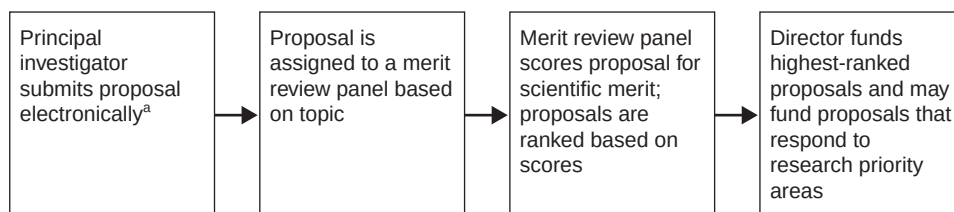
VA Intramural PTSD Research Studies Are Funded Primarily According to Scientific Merit

According to VA officials, intramural research proposals, including those on PTSD, are reviewed and funded in VA's Merit Review Program and VA's CSP primarily according to scientific merit.

VA's Merit Review Program

Intramural research proposals submitted to VA's Merit Review Program are reviewed through a series of steps prior to funding. See figure 4 for an overview of the submission, review, and funding process for proposals submitted to the Merit Review Program. (For more detailed information on this process, see app. II.)

Figure 4: Overview of Submission, Review, and Funding Process in Department of Veterans Affairs' (VA) Merit Review Program



Source: GAO analysis of VA documents and GAO interviews with VA officials.

^aProposals are submitted electronically to grants.gov, the government's central grant identification and proposal portal. Proposals are then transferred to eRA Commons, an electronic system for grant administration functions, for VA processing and review.

First, investigators submit proposals electronically. Investigators typically submit Merit Review Program proposals to grants.gov, the government's central grant identification and proposal portal,³⁰ in response to a request for proposals. Submitted proposals are then transferred to eRA Commons, an electronic system for grant administration functions, for VA processing and review.³¹

Second, each proposal is assigned to a merit review panel for evaluation. Each merit review panel reviews proposals in a specific research topic area, and is composed of panelists, typically associate-level professors, who are selected based on their expertise in this area.³² According to VA documents, as of 2010, there were a total of 35 merit review panels across VA's research and development services.³³ The merit review panels evaluate each proposal based on its scientific merit.³⁴ Panelists consider

³⁰Depending on the specific requirements of the request for proposal, a letter of intent (a preliminary outline of a research proposal) may be required prior to the submission of a research proposal.

³¹Electronic research administration, or eRA Commons, is managed and supported by the National Institutes of Health to provide support for the funding of research proposals.

³²Merit review panelists may or may not be employed by VA. According to VA officials, most merit review panelists have previous experience reviewing proposals. According to a VA document, the number of panelists on a merit review panel may vary. For example, the number of panelists on Rehabilitation's merit review panels ranges from 16 to 59.

³³Biomedical Laboratory and Clinical Science share the same merit review panels.

³⁴In addition, for Health Services, along with scientific merit, reviewers take into account research priority areas of Health Services when scoring proposals.

several criteria in evaluating the overall scientific merit of a proposal. (See table 4 for criteria used to determine scientific merit.)

Table 4: Scientific Merit Scoring Criteria in the Department of Veterans Affairs' (VA) Merit Review Program

Criteria	Description
Significance	Supports/advances the health and health care of veterans and research field in general; addresses important scientific question/area; makes a potential contribution to scientific literature.
Approach	Incorporates current scientific/theoretical bases; is hypothesis-driven; uses appropriate research design/methods for addressing hypothesis; ensures that feasibility of methods is clear.
Innovation	Addresses new concepts, gaps, or both, in the research area; addresses potential for impact of findings on existing field of research, treatment paradigms, or both.
Environment	Has appropriate knowledge/background and resources (e.g., equipment and staff) to ensure completion of study.
Feasibility	Provides sufficient evidence to determine that the proposed study can be successfully conducted and completed.
Investigator	Ensures that investigators involved in the proposed study are appropriately trained and have expertise in the proposed area of research.

Source: GAO analysis of VA information.

Third, the merit review panelists score the proposals to determine their rank. Each panelist provides a score to each of the proposals reviewed by the panel. The scores are averaged to create a “priority score” for the proposal.³⁵ (See app. II for specific scoring guidelines given to panelists in all research and development services.) All proposals scored by the merit review panel are then ranked by priority score among all of the proposal scores recently assigned by the merit review panel. The rank of the proposal is used to determine the “percentile” of the proposal.³⁶

³⁵For Health Services, prior to assigning a priority score for a proposal, merit review panelists vote on whether to approve, conditionally approve, or reject the proposal. Conditional approval means the proposal is approved pending additions or changes. Only approved and conditionally approved proposals are assigned a priority score.

³⁶According to VA, the percentile is calculated by the proposal’s rank, determined by its priority score in comparison to the scores of the current and previous three review cycles, minus 0.5, divided by the total number of applications being considered. For example, if a proposal received the fifth best priority score and there were a total of 60 proposals reviewed over the four cycles, the percentile for that application would be 5 minus 0.5 divided by 60, equaling .075.

Finally, research and development service directors determine how many proposals to fund. All of the proposals scored by all merit review panels in a research and development service in the review cycle are ranked together by their percentiles to be considered for funding. According to VA officials, research and development service directors typically fund up to the 25th percentile of proposals in a review cycle, beginning with those with the most scientific merit, although the number of proposals funded may vary depending on the budget. According to VA, research and development service directors may also choose to fund a small number of additional proposals at the margin that respond to research priority areas. For example, if the fundable range determined by a research and development service director was up to the 25th percentile, proposals at the 26th percentile related to research priority areas could also be considered for funding.³⁷

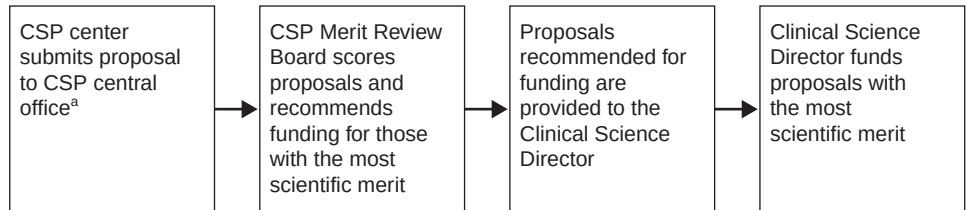
VA's Cooperative Studies Program

VA intramural research proposals submitted to CSP are reviewed and scored in a process similar to that of the Merit Review Program prior to consideration for funding. To help develop the CSP proposal, investigators are assisted by members of a CSP center,³⁸ a VA entity that provides guidance and support for research across multiple sites. (See fig. 5 for an overview of the process for submitting, reviewing, and funding a CSP proposal. For more information on ORD's CSP review process, see app. III.)

³⁷ After a proposal is approved for funding by the research and development service director, the proposal must undergo review by an institutional review board, an independent committee that reviews research based on ethical considerations. In addition, depending on the topic of the proposal, it may be reviewed by additional committees at this time, such as a data monitoring committee.

³⁸ There are nine CSP centers: VA operates five CSP Coordinating Centers to support multisite clinical trials and four Epidemiological Research and Information Centers to support epidemiology studies. In addition to receiving support from a designated CSP center, CSP proposals that involve drugs or medical devices also receive assistance from the CSP Clinical Research Pharmacy Coordinating Center, and CSP proposals that involve economic analysis receive support from VA's Health Economics Resource Center.

Figure 5: Overview of Submission, Review, and Funding for a Department of Veterans Affairs' (VA) Cooperative Studies Program (CSP) Proposal



Source: GAO analysis of VA documents and GAO interviews with VA officials.

^aPrior to submitting the proposal to CSP central office, the principal investigator must have a letter of intent approved by the Director of Clinical Science.

Before submitting a research proposal, investigators submit a letter of intent, or a preliminary outline of a proposal, to the Director of Clinical Science to be approved for planning a CSP proposal.³⁹ Based on the merit of the letter of intent, as determined by three or more reviewers,⁴⁰ the Clinical Science Director decides whether to fund planning efforts to develop a CSP proposal.⁴¹

When the principal investigator receives approval to begin planning efforts, the Clinical Science Director assigns a CSP center to provide statistical and methodological guidance to the investigator. The director of the CSP center designates a project manager and methodologist, such as a person with expertise in biostatistics, to provide guidance to the principal investigator. The Clinical Science Director, with recommendations from the principal investigator, then forms a planning committee of additional experts to assist in developing a CSP proposal. The planning committee develops a CSP proposal over the course of two planning meetings.

Once a proposal is developed, the CSP center, on behalf of the principal investigator, submits a hard copy proposal to the CSP central office for

³⁹ A letter of intent typically contains an outline of the proposed research study, including justification for multiple sites where the research will be conducted and a list of experts who can assist in the initial planning efforts of the research study.

⁴⁰ Reviewers of letters of intent are selected based on their expertise in areas related to the topic of the letter of intent.

⁴¹ Planning efforts include travel funds for personnel involved in developing the proposal. According to VA, there are two planning meetings that involve approximately 15 people.

evaluation by the Cooperative Studies Scientific Merit Review Board.⁴² This board consists of reviewers who have extensive experience in clinical research and the conduct of clinical trials or epidemiology studies.⁴³ Reviewers evaluate CSP proposals based on scientific merit. According to VA, the scientific merit of a CSP proposal is defined by the importance of the proposal, its feasibility, the clarity and achievability of its objectives, the adequacy of the plan of investigation, the correctness of the technical details, and the adequacy of the safeguards for the welfare of the patients.⁴⁴ Based on these criteria, reviewers discuss the general scientific merit of the proposal. Reviewers vote on whether to unconditionally approve, conditionally approve, reject or defer with recommendation for resubmittal, or reject each proposal. (See table 5 for an overview of funding recommendations provided by the board.)

Table 5: Overview of Funding Recommendations Provided by the Department of Veterans Affairs' (VA) Cooperative Studies Scientific Merit Review Board

Recommendation for funding	Definition
Unconditional approval	The proposal is approved without changes or additions to the proposal.
Conditional approval	The proposal is approved pending certain changes or additions to the proposal.
Rejection or defer with recommendation for resubmittal	The proposal is considered to be worthwhile, but is in need of major revisions. A revised proposal can be resubmitted to the Clinical Science Director.
Rejection	The proposal is rejected. The principal investigator must submit a new request for planning to submit a revised proposal.

Source: GAO analysis of a VA document.

⁴²CSP proposals are currently not submitted electronically; however, ORD officials estimate that electronic submission of CSP proposals through eRA Commons will begin in fall 2011.

⁴³According to a VA document, members of the Cooperative Studies Scientific Merit Review Board serve 4-year terms, and ad hoc members can be added depending on specific expertise that may be needed to review a proposal. As of October 2010, there were six members of the Cooperative Studies Scientific Merit Review Board.

⁴⁴CSP proposals are also reviewed by a human rights committee at the designated CSP center to determine if the protection of patients' rights and welfare is adequate. CSP proposals must be approved by a human rights committee prior to being funded.

After the reviewers vote, they each provide scores for a proposal recommended for funding based on scientific merit.⁴⁵ The scores are then averaged to provide a priority score for a proposal. Finally, the Clinical Science Director considers the priority scores of all the proposals in that review cycle and selects the proposals with the strongest priority scores for funding. According to VA officials, the number of proposals funded may vary depending on the budget.⁴⁶

VA Has Established a Standardized Process to Review All Relevant PTSD Research Outcomes and Incorporate Them into a PTSD CPG

The VA/DOD Evidence-Based Practice Work Group, which is responsible for developing and updating all of VA's CPGs, has a standardized and reproducible process to review all relevant research outcomes when developing or updating all CPGs, including the PTSD CPG. To develop or update a CPG, the VA/DOD Evidence-Based Practice Work Group identifies and assigns a group of VA and DOD clinical leaders and experts who are knowledgeable in the subject area to work on the CPG.⁴⁷ Generally, the process to develop or update a CPG consists of the following steps.

- First, the assigned group of VA and DOD clinical leaders and experts identifies "clinical questions" that will be answered in the CPG. According to VA officials, clinical questions can be either broad or specific. For example, the 2004 PTSD CPG contained clinical questions regarding whether early intervention is more effective than later intervention, and whether certain interventions, such as different psychotherapies, are more effective than others.
- Second, in order to minimize bias, an external contractor conducts a systematic review of relevant research and selects and summarizes the most methodologically rigorous research studies that are applicable to each of the clinical questions.

⁴⁵Scores are given only to conditionally and unconditionally approved proposals.

⁴⁶After a CSP proposal has received approval for funding, the proposal must undergo additional steps before study subjects are enrolled. For example, the proposal must be reviewed by an institutional review board, and an executive committee meets to review the operational and monitoring aspects of the study.

⁴⁷In addition, representatives from VA's Office of Patient Care Services are responsible for identifying VA and DOD clinical leaders.

-
- Third, after receiving summaries of the studies with the highest level of evidence, the VA and DOD group of clinical leaders and experts rates the research using an established grading scheme that considers
 - the level of evidence of each research study—the scope and methodological rigor of an individual study;
 - the overall quality of evidence—the overall quality of all of the research that addresses a particular clinical question, considering the level of evidence of all the studies considered; and
 - the net effect of an intervention—according to the collective results of the studies considered, the intervention’s benefits minus the intervention’s harms.
 - Finally, the assigned group of VA and DOD clinical leaders and experts assigns a grade to each evidence-based recommendation based on an assessment of the overall quality of evidence and the net effect of the intervention. (See app. IV for a detailed description of the process used to develop evidence-based VA/DOD CPGs.)

The process for conducting a systematic review of research outcomes to develop or update a CPG is repeated as often as is deemed necessary by the VA/DOD Evidence-Based Practice Work Group according to its written procedures and designated time frames.⁴⁸ According to VA/DOD Evidence-Based Practice Work Group documents, routine updates to the CPGs should ideally occur approximately every 2 years. However, updates to CPGs often do not occur every 2 years, and VA officials told us that some CPGs are updated more frequently than others based on availability of resources and priority areas. Additionally, VA officials reported that a CPG will be immediately updated if any evidence-based recommendation contained in it is identified as harmful to patients.

According to VA, the VA/DOD Evidence-Based Practice Work Group approved an update to the 2004 PTSD CPG on October 25, 2010, and published the update on VA’s Web site on November 17, 2010.⁴⁹ According

⁴⁸ According to VA, the development or update of a CPG typically takes 18 months.

⁴⁹ According to VA, the update of the PTSD CPG mainly strengthens the evidence that was already contained in the 2004 PTSD CPG. According to a VA official, the updated PTSD CPG will include a module on complementary alternative medicine, which was not included in the 2004 PTSD CPG.

to VA officials, the systematic process outlined above was used to review all relevant research outcomes and make evidence-based recommendations for PTSD services to both develop and update the PTSD CPG.

VA Reviewed Research Outcomes and Used Existing Resources in Determining Which PTSD Services to Require Its Facilities to Provide or Make Available to Veterans

According to VA officials, the decision to require that cognitive processing therapy and prolonged exposure therapy be made available to veterans diagnosed with PTSD at VA facilities—as indicated in the Handbook, which established certain requirements for mental health services within VA—was based on a review of research outcomes and the availability of existing resources.

- **Review of research outcomes.** According to VA, agency officials and qualified subject matter experts reviewed relevant research outcomes and the quality of the research to determine the most efficacious PTSD treatments available when determining which PTSD services to include in the Handbook and make available to veterans. Specifically, VA officials told us that their decision to include cognitive processing therapy and prolonged exposure therapy in the Handbook was influenced by the fact that both of these had been graded as level “A” treatments in the 2004 PTSD CPG (indicating that the intervention is always indicated and acceptable).⁵⁰ Furthermore, VA officials said that these two therapies had greater evidence supporting their effectiveness than other PTSD services also graded as level “A” in the 2004 PTSD CPG.⁵¹ In addition, VA officials added that their decision was validated by the results of a VA-commissioned Institute of Medicine study published in 2008 that reviewed the evidence for existing PTSD treatments. According to VA, the study found that cognitive processing therapy and prolonged exposure therapy were considered efficacious treatments for PTSD.⁵² While the Institute of

⁵⁰In the CPG, cognitive processing therapy is graded a level “A” treatment specifically for female sexual assault-related PTSD. However, VA officials told us that they also consider cognitive processing therapy to be effective for PTSD in veterans. See app. IV for a detailed description of the process used to determine grades for evidence-based recommendations.

⁵¹Two other psychotherapies, stress inoculation training and eye movement desensitization and reprocessing, were also graded as level “A” treatments for PTSD in the 2004 PTSD CPG, but were not included in the Handbook.

⁵²Institute of Medicine, *Treatment of Posttraumatic Stress Disorder: An Assessment of the Evidence* (Washington, D.C., 2008). The Institute of Medicine is an independent, nonprofit organization that works outside of government to provide authoritative advice to decision makers and the public. The Institute of Medicine found that exposure therapies, including prolonged exposure therapy and elements of cognitive processing therapy, are efficacious treatments for PTSD.

Medicine report was released after VA had already decided to include cognitive processing therapy and prolonged exposure therapy in the Handbook, VA officials explained that the Institute of Medicine report was the basis for the decision not to include other PTSD services in the Handbook.

- **Availability of existing resources.** VA officials told us that prior to issuing the Handbook in 2008, VA had already begun investing considerable resources to implement national training programs for cognitive processing therapy and prolonged exposure therapy in 2006 and 2007, respectively. VA officials said that they decided to implement the national training programs because VA realized the need to create sufficient capacity so that evidence-based PTSD treatments could be available to veterans throughout the VA system. VA explained that the national training programs were rolled out in advance of the Handbook's issuance as part of the implementation of VA's *Comprehensive Veterans Health Administration Strategic Plan for Mental Health Services*, which called for rapid implementation of evidence-based treatments. VA did this to ensure that it had the capacity to provide cognitive processing therapy and prolonged exposure therapy to all veterans with PTSD for whom these treatments were clinically appropriate.⁵³ VA officials said that they were able to begin implementing national training programs for cognitive processing therapy in 2006 and prolonged exposure therapy in 2007 because VA had qualified instructors to administer the programs and money available to fund them.⁵⁴

⁵³VA officials reported that incorporating cognitive processing therapy and prolonged exposure therapy into the Handbook helped ensure that clinicians who had been trained in these therapies prior to development of the Handbook would be able to offer and provide them in VA facilities as needed. In May 2010, VA's Office of Inspector General reported that as of November 17, 2009, the total number of mental health practitioners who had completed either the cognitive processing therapy or the prolonged exposure therapy training was 3,086. See Department of Veterans Affairs, Office of Inspector General, *Healthcare Inspection: Progress in Implementing the Veterans Health Administration's Uniform Mental Health Services Handbook* (Washington, D.C., 2010).

⁵⁴To help implement VA's *Comprehensive Veterans Health Administration Strategic Plan for Mental Health Services* (November 2004), VA allocated additional resources to fund mental health strategic plan initiatives in fiscal years 2005 and 2006. According to VA officials, a part of these additional resources was used to pay for the national cognitive processing therapy and prolonged exposure therapy training programs until the costs of the programs could be integrated into VA's congressional budget submission.

Unlike the written and standardized process that the VA/DOD Evidence-Based Practice Work Group established to develop CPGs, VA does not have a formal written process or framework to explain its decision for including cognitive processing therapy and prolonged exposure therapy in the Handbook.⁵⁵ VA officials explained that they followed a process when choosing cognitive processing therapy and prolonged exposure therapy, but added that clinical decision-making processes are not typically expected to be documented in a formal manner.

VA officials told us that they plan to assess the implementation of the Handbook and will update PTSD requirements in it as needed or as new information or unexpected obstacles arise in the future.⁵⁶ VA officials stated that they are currently clarifying the language regarding some of the requirements, but do not plan to revise any of the requirements relating to PTSD services at this time.

Agency Comments

We provided a draft of this report to VA and received technical comments, which we incorporated into our report as appropriate.

We are sending a copy of this report to the Secretary of Veterans Affairs. The report also is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or williamsonr@gao.gov. Contact points for our Offices

⁵⁵However, VA officials provided documentation regarding consultation with experts and a list of VA entities that participated in reviewing the Handbook.

⁵⁶According to VA officials, VA policies must be recertified every 5 years to remain in effect. The Handbook must be recertified on or before September 2013.

of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix V.

Sincerely yours,

A handwritten signature in black ink, reading "Randall B. Williamson". The signature is written in a cursive style with a large, stylized "R" and "W".

Randall B. Williamson
Director, Health Care

Enclosures – V

Appendix I: VA Research Centers and Programs That Conduct or Support PTSD Research

In addition to post-traumatic stress disorder (PTSD) research studies that are conducted by individual Department of Veterans Affairs (VA) investigators, or researchers, VA also funds a number of research centers or programs that conduct or support PTSD research. See table 6 for a description of these VA research centers and programs.

Table 6: Department of Veterans Affairs (VA) Research Centers and Programs That Conduct or Support Post-Traumatic Stress Disorder (PTSD) Research

VA research centers/programs	Description	Established by Congress?	Number of centers or programs with a primary focus on PTSD
Office of Mental Health Services			
The National Center for PTSD	Advances the clinical care and social welfare of veterans through research, education, and training in the science, diagnosis, and treatment of PTSD and stress-related disorders.	Yes	1 ^a
Centers of Excellence	Research the causes and treatments of mental disorders and use the dissemination of education to implement new knowledge into routine VA clinical practices.	Yes	2
Mental Illness Research, Education, and Clinical Centers	Research the causes and treatments of mental disorders and use education to implement knowledge into routine clinical practice in VA.	Yes	4
Office of Research and Development			
Centers of Excellence	Create or maintain a core program of investigators to support and facilitate the development of research studies and train and mentor new investigators.	No	8
Quality Enhancement Research Initiative Program	Enhances the quality and outcomes of VA health care by implementing research findings and evidence-based recommendations into routine clinical practice.	No	1 ^b
Research Enhancement Award Programs	Support groups of VA investigators that address specific medical problems of veterans to promote innovative research, train new medical research investigators, and foster new research collaborations among investigators.	No	1

Source: GAO analysis of VA information.

^aThe National Center for PTSD, headquartered in White River Junction, Vermont, has seven divisions in five locations across the country.

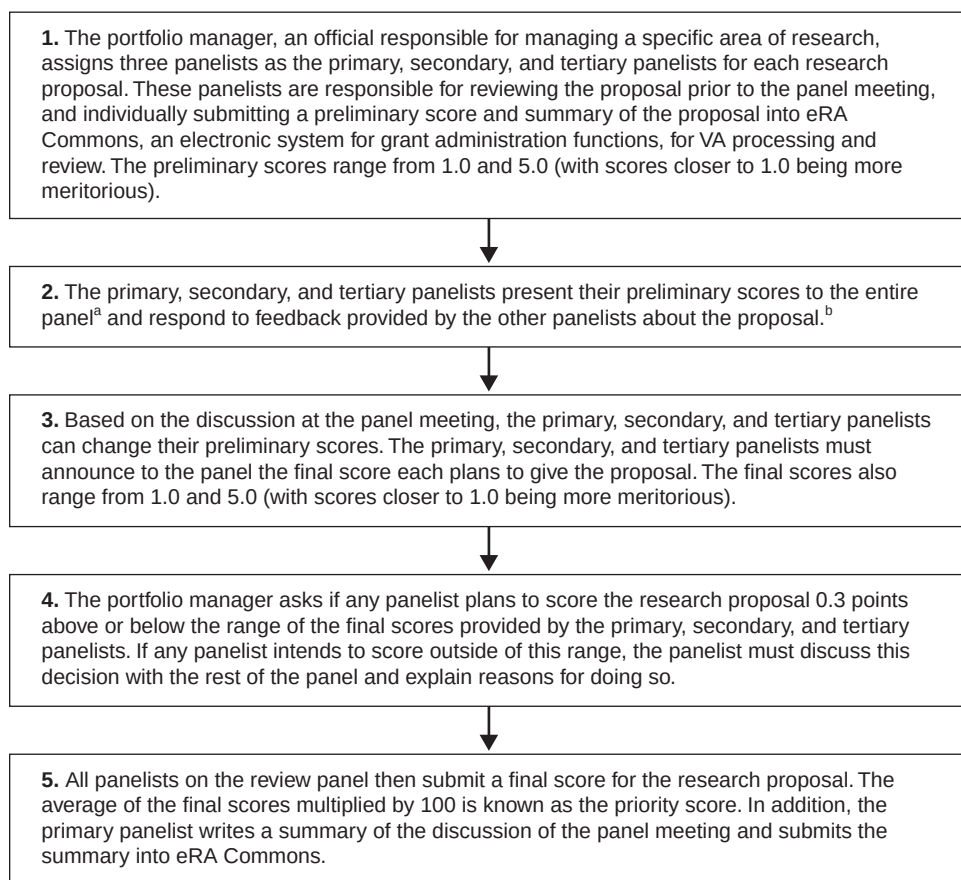
**Appendix I: VA Research Centers and
Programs That Conduct or Support PTSD
Research**

^bAlthough the Mental Health Quality Enhancement Research Initiative (one of nine Quality Enhancement Research Initiative Centers) focuses on depression and schizophrenia, Office of Research and Development officials stated that within the past few years it has become more involved with PTSD research.

Appendix II: The Review Process for VA's Merit Review Program

Research proposals submitted to the Department of Veterans Affairs' (VA) Merit Review Program are evaluated in merit review panels that each review proposals in a specific research topic area. Each merit review panel is comprised of panelists, typically associate-level professors, who are selected based on their expertise in the area. Panelists are responsible for scoring proposals based on scientific merit to provide funding recommendations. See figure 6 for a detailed description of the Merit Review Program's process for reviewing research proposals and table 7 for the Merit Review Program's scoring guidelines.

Figure 6: Summary of the Department of Veterans Affairs' (VA) Merit Review Process for the Merit Review Program



Source: GAO analysis of VA documents and GAO interviews with VA officials.

^aAccording to VA's policy, panelists who have a conflict of interest with a given proposal are required to leave the meeting before the proposal is discussed and do not score the proposal. According to VA, a conflict of interest exists when a reviewer has an interest in a research proposal that is likely to bias his or her evaluation of it. Panelists are expected to inform the portfolio manager if they have a conflict of interest.

^bIn some instances, research proposals are streamlined, meaning that they are evaluated only by the primary, secondary, and tertiary panelists, and are not discussed by the entire merit review panel. Proposals may be streamlined if the average of the primary, secondary, and tertiary panelists' preliminary scores falls in the upper half of the range of scores, indicating less merit. According to VA officials, proposals with a preliminary score of lower than 2.2, indicating very good or excellent, are also streamlined for two research and development services. (See table 7 for merit review process scoring guidelines.) In these instances, the administrator of the merit review panel meeting asks the panelists if anyone has an objection to streamlining the proposal. If a panelist objects, the proposal is discussed in the merit review panel meeting and it is not streamlined. Streamlined proposals with preliminary scores that fall in the upper half of the range of scores, indicating less merit, are not considered for funding.

**Appendix II: The Review Process for VA's
Merit Review Program**

Table 7: Scoring Guidelines for the Department of Veterans Affairs' (VA) Merit Review Program

Scoring range and grade	Description
1.0 – 1.5 Excellent	Proposed research addresses important scientific area that lacks needed knowledge. Hypothesis(es) is clearly stated and research design/methodology is appropriate. Research is innovative, representing state-of-the-art science. Potential findings may have a vital role in advancing the health and health care of veterans and research in general. Resources listed suggest a very high probability of the study's completion.
1.6 – 2.2 Very good	Proposed research addresses important scientific area. Hypothesis(es) is clearly stated and the research design/methodology is appropriate with a few minor exceptions. Potential findings may have an important role to the health and health care of veterans and research in general. Resources listed suggest a high probability of the study's completion.
2.3 – 2.8 Good	Proposed research addresses a valid area of investigation. Hypothesis(es) is clearly stated, but research design/methodology contains key flaws that should be corrected. Potential findings may contribute to the health and health care of veterans and research in general. Resources listed suggest that the study could be completed.
2.9 – 3.4 Fair	Proposed research requires further preliminary data to warrant investigation as a viable area of research. Hypothesis(es) is not clear, research design/methods contain significant flaws, or both. It is not clear how potential findings would contribute to the health and health care of veterans and research in general. It is unclear whether the resources listed are sufficient to ensure study completion.
3.5 – 5.0 Poor	Proposed research does not appear to address an important scientific question/area. Hypothesis(es) is not clearly stated, research design/methodology is inappropriate or contains uncorrectable flaws, or both. Design/methodological limitations hinder any significant conclusions that would contribute to the health and health care of veterans, research in general, or both. Resources listed do not suggest that the study will be completed.

Source: GAO analysis of VA documents.

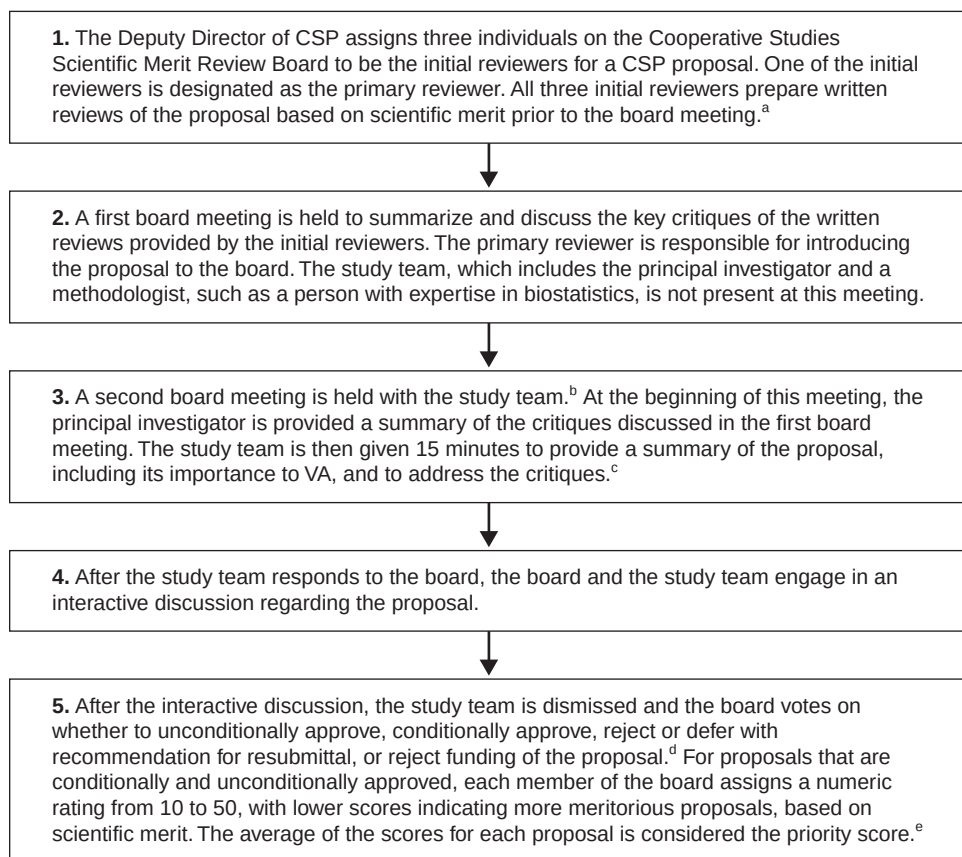
Appendix III: The Review Process for VA's Cooperative Studies Program

Research proposals submitted to the Department of Veterans Affairs' (VA) Cooperative Studies Program (CSP) are reviewed and scored by the Cooperative Studies Scientific Merit Review Board. Reviewers on the board are chosen based on their expertise in clinical or epidemiological research. They typically serve 4-year terms, and ad hoc members can be added depending on specific expertise that may be needed to review a proposal. According to VA, as of October 2010, there were six reviewers on the board.

During the research proposal review process, the study team—which includes the lead researcher (referred to as the principal investigator) and a methodologist, such as a person with expertise in biostatistics—has an interactive discussion with the board regarding the proposal.¹ Reviewers evaluate CSP proposals based on scientific merit and provide scores to reflect their funding recommendations. See figure 7 for a detailed description of the review process for CSP research proposals.

¹The study team may also include a health economist, in cases where a CSP proposal involves economic analysis. In addition, the principal investigator may ask the Clinical Science Director to allow other consultants to be a part of the study team, as necessary.

Figure 7: Summary of the Department of Veterans Affairs' (VA) Cooperative Studies Program (CSP) Review Process



Source: GAO analysis of VA documents and GAO interviews with VA officials.

^aAccording to a VA document, the primary reviewers are typically a biostatistician and a clinician. Reviewers are asked to comment on the importance of the proposal, its feasibility, the clarity and achievability of its objectives, the adequacy of the plan of investigation, the correctness of the technical details, the adequacy of the safeguards for the welfare of the patients, and any other pertinent features of the proposal. According to VA, these criteria are components of scientific merit.

^bFor CSP proposals that involve economic analysis, a health economist is also present at the board meeting to discuss the proposal. In addition, the principal investigator may ask the Clinical Science Director to allow consultants to be present at the board meeting if review of the proposal requires expertise in a specific area.

^cAccording to VA, if there are any economic issues raised relating to the proposal, the study team will be given an additional 5 minutes to address these issues with a health economist.

**Appendix III: The Review Process for VA's
Cooperative Studies Program**

^dAccording to a VA document, unconditional approval means a proposal is approved by the board without changes and is recommended for funding. Conditional approval means that the proposal is approved by the board pending certain changes or additions to the proposal. Reject or defer with recommendation for resubmittal means the board considers the proposal to be worthwhile, but it is need of major revisions. In this case, if the principal investigator chooses to submit a revised proposal, the Clinical Science Director may waive the requirement to submit a letter of intent. If the board rejects the proposal, the principal investigator must submit a new letter of intent to resubmit a revised proposal.

^eAfter the board scores the proposal, a human rights committee typically provides a general assessment of the protection of patients' rights and welfare as described in the proposal. For studies with unique ethical considerations, this review may occur prior to the review by the Cooperative Studies Scientific Merit Review Board.

Appendix IV: The Process for Developing VA/DOD Evidence-Based Clinical Practice Guidelines

In 1999, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) formed the VA/DOD Evidence-Based Practice Work Group to issue joint VA/DOD clinical practice guidelines (CPG)—tools that provide guidance and evidence-based recommendations to clinicians regarding the most effective interventions and services for a variety of health care topics.¹ To develop or update a CPG, the VA/DOD Evidence-Based Practice Work Group has a standardized process to ensure that systematic reviews of relevant research outcomes are conducted in order to formulate evidence-based recommendations for prevention, assessment, and treatment services.

To develop or update a CPG, the VA/DOD Evidence-Based Practice Work Group identifies two clinical leaders—one from VA and one from DOD—who then help identify not more than 15 to 20 other experts in the subject area to form a “guideline working group.”² A member of the VA/DOD Evidence-Based Practice Work Group is also selected to be an evidence chaperone for each CPG to ensure that conformity to prevailing standards for conducting high-quality systematic reviews is upheld.³

To determine the scope of the CPG, the guideline working group, the evidence chaperone, and a facilitator are responsible for identifying clinical questions that are to be answered by a systematic review of relevant research outcomes.⁴ According to VA officials, clinical questions

¹Evidence-based care refers to approaches that have consistently been shown in controlled research to be effective for a particular condition or conditions. The VA/DOD Evidence-Based Practice Work Group makes decisions about which clinical practice guidelines for specific conditions will be developed and oversees their development. As of August 2010, the VA/DOD Evidence-Based Practice Work Group had issued 24 CPGs on conditions such as chronic heart failure and major depressive disorder. Since VA and DOD issue the CPGs in a joint effort, they are intended to be used by both VA and DOD clinicians. The VA/DOD Evidence-Based Practice Work Group is supported by VA’s Office of Quality and Performance and the U.S. Army Medical Department’s Office of Quality Management.

²In addition, representatives from VA’s Office of Patient Care Services are responsible for identifying VA and DOD clinical leaders.

³VA and DOD designees from the VA/DOD Evidence-Based Practice Work Group, with assistance from VA’s Office of Patient Care Services, are responsible for selecting the VA and DOD clinical leaders and the evidence chaperone. In addition, they also select another member of the VA/DOD Evidence-Based Practice Work Group to monitor the development of the CPG.

⁴The facilitator is also responsible for keeping the guideline working group focused during meetings and to ensure that it focuses on the quality of research outcomes when formulating evidence-based recommendations in the CPG.

can be both broad and specific. For example, the 2004 post-traumatic stress disorder CPG contained clinical questions regarding whether early intervention is more effective than later intervention and whether certain interventions, such as different psychotherapies, are more effective than others.⁵

According to VA, in order to answer these clinical questions, an external evidence center—an entity that conducts systematic reviews of research on a variety of topics—is contracted to collect and review all relevant research (including, but not limited to, VA- and DOD-sponsored research) to assess its applicability to each clinical question under consideration using explicit and reproducible methods.⁶ The evidence center then focuses its review on the best available research, that is, high-quality, methodologically rigorous studies that address health issues that impact VA and DOD populations and consider the effectiveness as well as the harms and benefits of the intervention at issue. According to VA officials, the evidence center provides summaries of only the best available research to the guideline working group for review.⁷

After receiving the summaries, the guideline working group reviews the research in sequential steps using an established rating scheme developed by the U.S. Preventive Services Task Force to formulate evidence-based recommendations.⁸ See figure 8 for an overview of the steps that the guideline working group uses to formulate evidence-based recommendations.

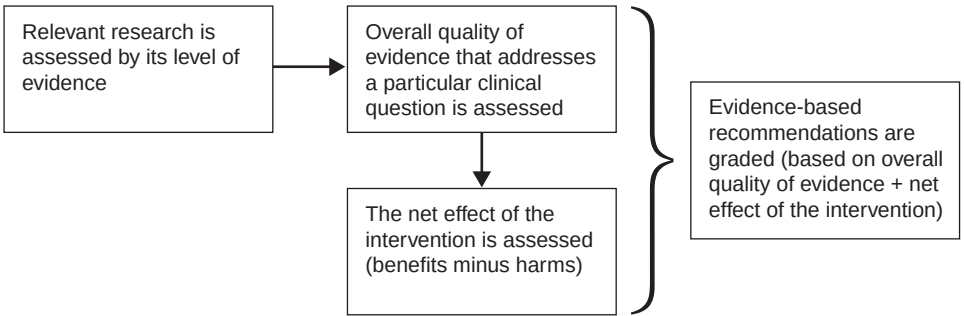
⁵The post-traumatic stress disorder CPG is formally known as *The VA/DOD Clinical Practice Guideline for the Management of Post-Traumatic Stress* (January 2004).

⁶According to a VA official, an external evidence center is used to minimize bias.

⁷The evidence center provides summaries of research of lower quality only if no higher-quality research is available.

⁸The U.S. Preventive Services Task Force was first convened by the Department of Health and Human Services' Public Health Service in 1984, and since 1998 has been sponsored by the Department of Health and Human Services' Agency for Healthcare Research and Quality. The U.S. Preventive Services Task Force uses explicit criteria to grade the scientific evidence for a broad range of clinical services and develop evidence-based recommendations for clinicians and health systems. While the U.S. Preventive Services Task Force updated its criteria in May 2007, the VA/DOD Evidence-Based Practice Work Group currently uses U.S. Preventive Services Task Force criteria developed prior to May 2007.

Figure 8: Overview of the Process Used by the Guideline Working Group Established by the Department of Veterans Affairs (VA)/Department of Defense (DOD) Evidence-Based Practice Work Group to Grade Evidence-Based Recommendations for Clinical Practice Guidelines



Source: GAO analysis of VA/DOD documents and GAO interviews with VA officials.

Level of evidence. First, the guideline working group reviews the summaries to identify the level of evidence, or the level of methodological rigor. For example, research studies that have the highest quality are categorized as “I” (indicating at least one properly done randomized controlled trial), while research studies of the lowest quality are categorized as “III” (indicating that the research reflects the opinion of respected authorities, descriptive studies, case reports, and expert committees). (See table 8.)

Table 8: Categorization of Ratings Used by the Guideline Working Group Established by the Department of Veterans Affairs (VA)/Department of Defense (DOD) Evidence-Based Practice Work Group to Identify the Level of Evidence of Research Outcomes

Rating	Description
I	At least one properly done randomized controlled trial
II-1	Well-designed controlled trial without randomization
II-2	Well-designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Source: VA/DOD document.

Overall quality of research. After determining the level of evidence of individual research studies, the guideline working group makes a

determination regarding the overall quality of all of the research that addresses a particular clinical question. The overall quality takes into account the number, quality, and size of all of the individual research studies together as well as the consistency of the results between research outcomes to determine the collective overall strength of the research. Based on this review, the guideline working group determines the overall quality of the evidence to be good, fair, or poor.⁹ (See table 9.)

Table 9: Categorization of Ratings Used by the Guideline Working Group Established by the Department of Veterans Affairs (VA)/Department of Defense (DOD) Evidence-Based Practice Work Group to Determine the Overall Quality of Research

Rating	Description
Good	High-grade evidence (I or II-1) linked to health outcome
Fair	High-grade evidence (I-or II-1) linked to intermediate outcome Or Moderate-grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Source: VA/DOD document.

Net effect of the intervention. For interventions that were supported by studies of “fair” or “good” overall quality, the guideline working group evaluates the benefits and the potential harms to determine the net effect of the intervention.¹⁰ The net effect of an intervention takes into account the benefits of the intervention minus the harms to determine the overall potential clinical benefit that the intervention may provide to patients. The net effect of the intervention ranges from “substantial” (meaning the benefit substantially outweighs the harm) to “zero or negative” (meaning it has no impact or a negative impact on patients). (See table 10.)

⁹The overall quality of the research is considered “good” when the research outcomes are consistent from a number of higher-level research studies and have been conducted across a broad range of populations, thereby providing a high degree of confidence that the research outcomes are true. A “fair” overall quality indicates that the research outcomes could have been a result of true effects or biases present across some or all of the research studies. A “poor” rating for overall quality indicates that any conclusion about the research outcomes is uncertain because of serious methodological shortcomings, sparse data, or inconsistent results.

¹⁰The net effect of the intervention of research outcomes that are found to be of poor overall quality is not assessed because the evidence is insufficient to make a recommendation for or against routinely providing the intervention.

**Appendix IV: The Process for Developing
VA/DOD Evidence-Based Clinical Practice
Guidelines**

Table 10: Categorization of Ratings Used by the Guideline Working Group Established by the Department of Veterans Affairs (VA)/Department of Defense (DOD) Evidence-Based Practice Work Group to Determine the Net Effect of the Intervention as Described in the Research

Rating	Description
Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering <i>Or</i> A large impact on an infrequent condition with a significant impact on the individual patient level
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering <i>Or</i> A moderate impact on an infrequent condition with a significant impact on the individual patient level
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering <i>Or</i> A small impact on an infrequent condition with a significant impact on the individual patient level
Zero or negative	Negative impact on patients <i>Or</i> No relative impact on either a frequent condition with a substantial burden of suffering or an infrequent condition with a significant impact on the individual patient level

Source: VA/DOD document.

Grade of evidence-based recommendation. In the final step, the guideline working group uses its assessment of the overall quality of the evidence and the net effect of the intervention to grade evidence-based recommendations. (See table 11.)

Table 11: Grade of Evidence-Based Recommendation Assigned by the Guideline Working Group Established by the Department of Veterans Affairs (VA)/Department of Defense (DOD) Evidence-Based Practice Work Group Based on the Overall Quality of Evidence and the Net Effect of the Intervention as Described in the Research

Overall quality of evidence	The net benefit of the intervention			
	Substantial	Moderate	Small	Zero or negative
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I
Grade of recommendation	Description of recommendation			
A	A strong recommendation that the intervention is always indicated and acceptable			
B	A recommendation that the intervention may be useful/effective			
C	A recommendation that the intervention may be considered			
D	A recommendation that a procedure may be considered not useful/effective or may be harmful			
I	Insufficient evidence to recommend for or against—the clinician will use clinical judgment			

Source: VA/DOD document.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Staff Acknowledgments

In addition to the contact named above, Mary Ann Curran, Assistant Director; Susannah Bloch; Stella Chiang; Martha R. W. Kelly; Melanie Krause; Lisa Motley; Michelle Paluga; Rebecca Rust; and Suzanne Worth made key contributions to this report.

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