Adequacy of the Comprehensive Clinical Evaluation Program

A Focused Assessment

INSTITUTE OF MEDICINE

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Committee on the Evaluation of the Department of Defense
Comprehensive Clinical Evaluation Program

Division of Health Promotion and
Disease Prevention

INSTITUTE OF MEDICINE

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Contents

Executive Summary

On August 2, 1990, Iraq invaded Kuwait. Within 5 days the United States had begun to deploy troops to the Persian Gulf in Operation Desert Shield. In January 1991, UN coalition forces began intense air attacks against the Iraqi forces (Operation Desert Storm), on February 24, a ground attack was launched and within 4 days, Iraqi resistance crumbled. Almost 700,000 US troops participated in the Persian Gulf War. Following the fighting, the number of US personnel began to decline rapidly.

Most troops returned home and resumed their normal activities. Within a relatively short time, a number of those who had been deployed to the Persian Gulf began to report health problems they believed to be connected to their deployment. These problems included the symptoms of fatigue, memory loss, severe headaches, muscle and joint pain, and rashes.

In 1992 the Department of Veterans Affairs (VA) developed a Persian Gulf Registry to assist in addressing questions about health concerns of Persian Gulf veterans. Exposures, particularly those associated with oil well fires, were included as part of the history taking. By 1994, with continuing concern about potential health consequences of service in the Persian Gulf, the Department of Defense (DoD) implemented a clinical evaluation program similar to the VA's and named it the Comprehensive Clinical Evaluation Program (CCEP).

Also in 1994, DoD asked the Institute of Medicine (IOM) to assemble a group of medical and public health experts to evaluate the adequacy of the CCEP. This committee concluded that although overall "the CCEP is a comprehensive effort to address the clinical needs of the thousands of active-duty personnel who served in the Gulf War," specific recommended changes in

the protocol would help to increase its diagnostic yield. (See Appendix D for a complete set of recommendations.)

Late in 1995, DoD asked the IOM to continue its evaluation of the CCEP with special attention to the adequacy of the protocol as it related to (1) difficult-to-diagnose individuals and those with ill-defined conditions; (2) the diagnosis and treatment of patients with stress and psychiatric conditions; and (3) assessment of the health problems of those who may have been exposed to low levels of nerve agents. It is important to note what was not included in the committee charge. It was *not* the committee's charge to determine whether or not there is such an entity (or entities) as "Persian Gulf Illness" nor was it this committee's charge to determine whether or not there are long-term health effects from low-level exposure to nerve agents. These questions are more properly the subject for extensive scientific research.

Given the urgency surrounding the last question—the health problems of individuals with possible exposure to low levels of nerve agents—the committee addressed this issue first and separately, releasing its report, *Adequacy of the Comprehensive Clinical Evaluation Program: Nerve Agents,* in April 1997. The committee concluded that although the CCEP continues to provide an appropriate screening approach to the diagnosis of disease, certain refinements would enhance its value. A complete set of recommendations is found in Appendix F.

To complete the remaining portions of its charge, the committee convened two workshops on the relevant topics, heard presentations, reviewed written material, and received comments from leading scientific and clinical experts, representatives of DoD and the VA, the Presidential Advisory Committee, the General Accounting Office, and representatives of veterans groups.

A great deal of time and effort has been expended evaluating DoD's Comprehensive Clinical Evaluation Program. It has been reviewed by the President's Advisory Committee, the General Accounting Office, the Office of Technology Assessment, the Institute of Medicine, and many other organizations. As more is learned, it becomes easier to focus on the kinds of questions the CCEP should be asking. As Dr. Penelope Keyl said in her workshop presentation on the development of good screening instruments, progress made over time will necessitate new generations of screening instruments. This does not imply that the first instrument developed is bad, but rather that time leads to new knowledge, which leads to the ability to improve the instrument.

Such is the case with the CCEP. Over time, the CCEP and other programs have generated information that has increased our understanding and led us to focus on areas of importance for those concerned about the health consequences of Persian Gulf deployment. This information has enabled us to take a closer look, to make a more thorough examination of the system, and to identify areas in which change will be of benefit. The committee believes that such change is

healthy, that it reflects growth, and that it should be a natural part of any system having as one of its goals the delivery of high-quality health care services.

Change also occurs with individuals. It may be that as time passes or new information is released, some of those who have already participated in the CCEP will develop new concerns or problems. The committee hopes that DoD will encourage these individuals to return to the CCEP for further evaluation and diagnosis if they so desire.

CONCLUSIONS AND RECOMMENDATIONS

Medically Unexplained Symptom Syndromes

The committee spent time deliberating on the precise meaning of "difficult to diagnose" or "ill defined" as a description of a category of conditions. Difficult to diagnose is generally used to describe a condition for which special expertise is required to arrive at a diagnosis, but some of the conditions under consideration do not require such expertise. Chronic fatigue syndrome (CFS), fibromyalgia, and multiple chemical sensitivity are symptom complexes that have a great deal of overlap in the symptoms present in each condition. They are symptom-based, without objective findings. However, they are actually fairly well defined by operational criteria, even if they are medically unexplained. Despite the fact that they are medically unexplained, they may cause significant impairment, and they are conditions that are better understood through time (i.e., adequate evaluation of these disorders requires a longitudinal perspective that includes knowledge of previous services and responses to treatment). The committee decided, therefore, to refer to this spectrum of illnesses as *medically unexplained symptom syndromes.* This spectrum of illnesses may include those which are etiologically unexplained, lack currently detectable pathophysiological changes, and/or cannot currently be diagnostically labeled.

Medically unexplained symptom syndromes are often associated with depression and anxiety, yet this does not imply that the syndromes are psychiatric disorders. There remains a debate about how to distinguish these syndromes from psychiatric diagnoses. However, since most of the recommended treatments for medically unexplained symptom syndromes overlap with the pharmacological and behavioral treatments for psychiatric diagnoses, the committee believes that it is important to identify and evaluate the symptoms associated with these conditions and then treat those symptoms.

- **The committee recommends that when patients presenting with medically unexplained symptom syndromes are evaluated, the provider**

must have access to the full and complete medical record, including previous use of services.

In the area of medically unexplained symptom syndromes, it is sometimes not possible to arrive at a definitive diagnosis. It may be possible, however, to treat the presenting complaints or symptoms.

- **The committee recommends that in cases where a diagnosis cannot be identified, treatment should be targeted to specific symptoms or syndromes (e.g., fatigue, pain, depression).**
- **The committee recommends that the CCEP be encouraged to identify patients in this spectrum of illnesses early in the process of their disease. In addition, primary care providers should identify the patients' functional impairments so as to be able to suggest treatments that will assist in improving these disabilities.**

Stress

Stress is a major issue in the lives of patients within this spectrum of illness. Stress need not be looked at so much as a causative agent, but rather as a part of the condition of the patient that cannot be ignored. With medically unexplained symptom syndromes, the potential for stress proliferation is great among both the person deployed to the Persian Gulf and the family members.

Research has shown that stressors have been associated with major depression, substance abuse, and various physical health problems. Those deployed to the Gulf were exposed to a vast array of different stressors that carry with them their own potential health consequences. The current collection of exposure information does not adequately address an investigation of traumatic events to which the deployed soldier may have been exposed. In addition, media attention and reports by the military to Gulf War veterans that toxic exposure could have occurred are very stressful events. The stress associated with these reports needs to be recognized and addressed.

- **The committee recommends that the CCEP contain questions on traumatic event exposures in addition to the exposure information currently being collected. This would include the addition of open-ended questions that ask the patient to list the events that were most upsetting to him or her while deployed. Positive responses to questions regarding such events, as well as to other exposure questions, should be pursued with a *narrative inquiry*, which would address such items as the specific nature of the exposure; the duration; the frequency of repetition; the dose or**

intensity (if appropriate); whether the patient was taking protective measures and, if so, what these measures were; and the symptoms manifested.

- **The committee recommends that DoD providers acknowledge stressors as a legitimate but not necessarily sole cause of physical symptoms and conditions.**

Every soldier who goes to war will be subjected to major disturbing events since war involves death and destruction. There are certain jobs undertaken in the midst of war that, by their very nature, result in high stress (e.g., grave registration duty). The effect of stress associated with these jobs can be mitigated if approached properly. Such efforts, however, require time for the provider and the patient to interact. It is not possible to hand the patient a pamphlet or a questionnaire and expect that all necessary information will be revealed or understood.

- **The committee recommends that DoD provide special training and debriefing for those who are engaged in high-risk jobs such as jobs associated with the Persian Gulf experience.**
- **The committee recommends that DoD provide to each about-to-be deployed soldier, risk or hazard communication that is well developed and designed to provide information regarding what the individual can expect and the potentially traumatic events to which he or she might be exposed.**
- **The committee recommends that adequate time must be provided during initial interactions with patients in the CCEP in order to insure that all pertinent information is forthcoming.**

Screening

Depression is a condition that is common in primary care. Most individuals who experience depression continue to function, but if they are left untreated, their condition may deteriorate. Unlike many of the medically unexplained symptom syndromes, there are accepted and effective treatments for depression.

- **The committee recommends that there be increased screening at the primary care level for depression.**
- **Every primary care physician should have a simple standardized screen for depression. If a patient scores in the significant range, this person should be referred to a qualified mental health professional for further evaluation and treatment.**
- **If depression is identified, there has to be more questioning on exposure to traumatic situations.**

• **The committee recommends that any individual who reports any significant symptoms of posttraumatic stress disorder (PTSD) and/or a significant traumatic stressor should be referred to a qualified mental health professional for further evaluation and treatment.**

Substance abuse or misuse problems are prevalent in primary care. In addition, individuals under stress and/or with untreated depression or medically unexplained symptom syndromes may be at increased risk for substance abuse.

• **The committee recommends that every primary care physician have a simple, standardized screen for substance abuse. Every individual who screens positive should be referred for further evaluation and treatment.**

There are certain areas in which baseline assessments are of immense value in the clinical evaluation of an individual patient's status (e.g., pulmonary function and neurobehavioral testing). Changes in neurocognitive and peripheral nerve function are measured by comparing the individual's current status to a baseline measure. Individual baseline information is necessary because the variability across individuals is too great to identify a generalized "normal" screening level.

• **The committee recommends that DoD explore the possibility of using neurobehavioral testing at entry into the military to determine whether it is feasible to use such tests to predict change in functioning or track change in function during a soldier's military career.**

Program Evaluation

Most patients in the CCEP receive a diagnosis after completing a Phase I examination; some are referred to Phase II for evaluation; and a few have gone on to participate in the program at the Specialized Care Center (SCC). Information presented to the committee indicates that there is great variation across regions in the percentage of patients who are diagnosed with primary psychiatric diagnoses and medically unexplained symptom syndromes. A determination should be made as to why this variation exists. Although there may be many reasons, one explanation could relate to the consistency with which procedures for diagnosis and referral are implemented from facility to facility.

• **The committee recommends that an evaluation be conducted to examine (1) the consistency with which Phase I examinations are conducted across facilities; (2) the patterns of referral from Phase I to Phase II; and**

(3) the adequacy of treatment provided to certain categories of patients where there is the potential for great impact on patient outcomes when effective treatment is rendered (e.g., depression).

The SCC has provided evaluation and treatment to 78 patients since it was begun. A great deal of effort and thought has gone into the development of a program designed to help the patient understand his or her conditions and engage in behaviors most likely to result in improvement. The committee was asked to assess the effectiveness of this center, but realized that such an assessment depended on a number of factors that have not been well defined. What is the goal of the center—is it treatment, research, or education? Should a major consideration in the center's evaluation be cost-effectiveness? Should the numbers of those receiving care be taken into consideration and, if so, what are the barriers to patients accessing this level of care? What is the triage process by which individuals get referred to the SCC?

- **The committee recommends that a short-term (perhaps 5-year) plan be developed for the Specialized Care Center that would specify goals and expected outcomes.**

Coordination with the VA

Given that many now receiving services in the DoD health care system will eventually move to the VA health care system, it is important for there to be good communication between DoD and the VA. This may be particularly true in the areas of medically unexplained symptom syndromes and psychiatric disorders, where accurate diagnosis and/or assessment of response to treatment is important for positive patient outcomes.

- **The committee recommends that DoD explore ways to increase communication with the VA, particularly as it relates to the ongoing treatment of patients.**

Both providers and patients would benefit from increased educational activity regarding Persian Gulf health issues. Provider turnover within DoD is a factor that must be taken into consideration when examining the special health needs and concerns of active-duty personnel who were deployed to the Persian Gulf. Although efforts to educate providers were extensive at the time the CCEP was implemented, 3 years have passed and many new providers have entered the system. These individuals should be oriented to the special needs, concerns, and procedures involved, and all providers should be updated regularly.

The VA has developed a number of approaches to provider education which could serve as useful models. Interactive satellite teleconferences are available for medical center staff to discuss particular issues of concern. The VA conducts quarterly national telephone conference calls, directs periodic educational mailings to Persian Gulf Registry providers in each health facility, and conducts an annual conference on the health consequences of Persian Gulf service.

In addition to providers, there is a great need for education of and communication with individuals (and their families) who were deployed to the Gulf. These individuals are concerned about the potential impact of Persian Gulf deployment on their health, whether or not their health concerns will affect their military careers, their ability to obtain health insurance once they leave the service, and a number of other issues that need to be addressed.

- **The committee recommends that DoD examine the activities and materials for provider education developed by the VA to determine if some of the items might be used as educational approaches for DoD providers.**
- **The committee recommends that DoD mount an effort designed to educate providers to the fact that conditions related to stress are not necessarily psychiatric conditions. The committee recommends that depression be a topic of education for all primary care providers, with emphasis on the facts that depression is common, it is treatable, and individuals who experience depression can continue to function.**
- **The committee recommends that CCEP information be used to develop case studies that will help educate providers about Persian Gulf health problems.**
- **The committee recommends that DoD develop approaches to communication and education that address the concerns of individuals deployed to the Persian Gulf and their families.**

Determining the etiology(ies) of health problems experienced by those deployed to the Persian Gulf War may not always be possible. However, it is possible that treatment can be provided for many of the symptoms or conditions associated with some of these problems. The committee wishes, therefore, to emphasize the importance of adequate assessment of medically unexplained symptom syndromes and of traumatic event exposure, as well as screening for depression and for substance abuse. Such additions to the CCEP will enhance its ability to identify and, ultimately, treat the health problems being experienced by those who served in the Persian Gulf War.

Table 1 provides a summary of the committee's recommendations.

TABLE 1 Summary of Committee Recommendations

Topic	Recommendation
Medically unexplained symptom syndromes	• The provider evaluating these patients must have access to the complete medical record including prior treatment. • Rather than attempting to fit a treatment to a diagnosis, treatment should target specific symptoms or syndromes (e.g., pain, fatigue, depression). • A patient's functional impairments should be identified early to facilitate treatment.
Stress	• The initial CCEP examination should include questions regarding traumatic event exposure. Any positive response should be followed up with a narrative inquiry. • Stressors must be acknowledged as a legitimate but not necessarily sole cause of physical symptoms and conditions. • DoD should provide special training and debriefing for those engaged in high-risk jobs during deployment, e.g., graves registration. • DoD should provide risk or hazard communication to each about-to-be deployed soldier. • Adequate time must be provided for provider/patient interaction during CCEP examinations.
Screening	• There should be increased screening for depression at the primary care level. • Every physician should employ a simple, standardized screen for depression (e.g., BDI, Zung Scale, CES-D, IDD). • Patients who screen positive for depression should be referred for screening, further evaluation, and treatment. • Patients diagnosed with depression should be interviewed regarding traumatic exposure. • Patients identified with any significant PTSD symptoms and/or a significant traumatic stressor should be referred to a qualified mental health professional for further evaluation and treatment. • Every physician should employ a simple standardized screen for substance abuse (e.g., CAGE, brief MAST, T-ACE, TWEAK, AUDIT). • Every patient who screens positive for substance abuse should be referred for further evaluation and treatment. • DoD should explore feasibility of neurobehavioral testing at entry into military for usefulness in measuring change in function.

Continued