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EVALUATION OF WARTIME EXPOSURES, GULF WAR VETERAN HEALTH CONCERNS AND RELATED RESEARCH, AND UNANSWERED QUESTIONS

INTRODUCTION

This chapter examines health and science aspects of the question: “Why are Gulf War veterans ill?” and highlights some of the complexities around this issue. It begins with health-related decisions made before the 1990 deployment to Southwest Asia, continues with a review of health events of importance during the deployment, and concludes with a review of developments in the eight years since the Gulf War. This chronological perspective is an important one, as events during the time leading up to the deployment have ultimately affected the ability of scientists, researchers, and physicians to examine potential causes of illnesses among Gulf War veterans. Problems such as inadequate information about the range and extent of troop exposures, missing health records, and limited health screening seriously hinder the ability to conduct scientific research that can provide clear answers to why Gulf War veterans are ill. This chronology of events provided insights and observations into how DOD and VA fell short in their attempts to best protect the health and treat the illnesses of Gulf War veterans.

HEALTH ISSUES PRIOR TO THE GULF WAR DEPLOYMENT

BACKGROUND ON THE MILITARY HEALTH CARE SYSTEM’S ROLE IN MAINTAINING TROOP HEALTH

An understanding of the military health care system’s role in monitoring and protecting troop health is important to identifying pre-deployment factors that may have affected the health of Gulf War veterans. Military medicine differs from medicine practiced in the civilian context in several ways. For example, military physicians often care for service members as a group and are responsible for that group’s health as part of a military mission. They also are responsible for providing health information to commanders that is relevant to operational decisions. Such operational decisions can

have a specific health focus while advancing a military goal. For example, vaccinations or medicines may be administered on a mandatory basis to service members to protect them against an identified threat. Because a key aspect of such decisions is how they may affect these troops' health in the future, military physicians also need to ensure that detailed and accurate records are kept to document the implementation of these decisions.

The military's medical system also needs to ensure that all troops—whether on active duty or in the reserves—are healthy and ready to deploy rapidly to war or conflict situations by providing troops routine physical examinations, regular preventive care, and medical care when ill. The military medical system also employs aspects of preventive and occupational medicine to monitor troop health, reduce disease and, where possible, prevent injuries and deaths. Examples of these functions are educating troops on how to minimize potential health risks from exposure to toxic substances on the battlefield, conducting environmental sampling and using that information to minimize troop exposure to toxic compounds, and providing protective clothing and equipment. Although military medicine made efforts to monitor and protect troop health, the Gulf War experience shows that it could have done far more for that deployment. In the future, the efforts of the military medical system in this regard should be expanded and more rigorously implemented.

PRE-DEPLOYMENT MEDICAL EFFORTS TO PROTECT AGAINST BIOLOGICAL AND CHEMICAL WEAPONS THREATS

One way in which medical and operational decisions overlapped during Gulf War planning was in efforts to protect troops against likely chemical and biological weapons threats that could have resulted from battlefield encounters with Iraq. To help protect U.S. troops against this threat, the Secretary of Defense, in consultation with military physicians and health policy planners, decided to vaccinate some troops against the biological weapons agents anthrax and botulinum toxin, as well as to administer a medication, pyridostigmine bromide (or PB), to attempt to protect against some chemical warfare nerve agents. The anthrax vaccine that DOD used (and continues to use) on troops had been approved for this use by the U.S. Food and Drug Administration (FDA) and had been used for decades to protect individuals from contracting anthrax. However, the botulinum toxoid vaccine and PB were not FDA fully-approved products for use to protect against biological and chemical warfare agents.¹⁸⁷

BACKGROUND ON THE FDA AND INVESTIGATIONAL NEW DRUGS (INDS)

FDA regulates whether and how medicinal drugs and vaccines in the United States may be used.¹⁸⁸ A medical drug or vaccine that FDA has not approved for marketing or one used for a purpose other than that identified in FDA-approved labeling is considered to be “investigational.” Moreover, an investigational new drug (IND) application must be filed with the FDA in order to test an unapproved product in a clinical setting on human subjects or to test approved products for unapproved uses.¹⁸⁹ Prior to the Gulf War, FDA and DOD had closely collaborated in the use and

development of medical products under IND status under a joint Memorandum of Understanding dated May 1, 1987.¹⁹⁰

DOD EFFORTS TO ADMINISTER TWO INDs, BOTULINUM TOXOID VACCINE AND PB, DURING THE GULF WAR

DOD wanted to administer botulinum toxoid vaccine and PB, investigational new drugs, to some troops deploying to the Gulf War. Approximately 10,000 doses of the vaccine had already been safely administered from 1970 through 1990 to “laboratory professionals and public health professionals at risk of infection” from botulinum.¹⁹¹ PB was FDA approved to treat myasthenia gravis, a chronic disease characterized by muscle weakness, but not to protect against chemical weapons agents.¹⁹² However, DOD believed that there was sound scientific evidence that taking PB tablets could protect troops against some, although not all, chemical weapons agents that Iraq was believed to possess.¹⁹³

Although other NATO countries had used PB to protect their troops against some chemical warfare agents for years,¹⁹⁴ PB’s ability to protect humans against exposure to nerve agents is not fully understood. In lieu of studies of human exposure to nerve agents (which would present serious ethical questions), animal studies have been conducted. These studies demonstrate PB’s protective effect against animal (although not necessarily human) exposure to the nerve agents soman and tabun.¹⁹⁵ However, animal studies indicate that PB appears to be ineffective against the nerve agents sarin and VX.¹⁹⁶ At the time of the Gulf War, DOD made no distinction between the types of nerve agents that PB was considered to be effective against. Indeed, only in 1998 did DOD publicly acknowledge that PB should only be used as a pretreatment if the nerve agents soman or tabun were likely to be used against our troops, but not if other agents, such as sarin, were likely threats.¹⁹⁷

In addition to the limits on PB’s likely effectiveness to protect against chemical warfare agents, it was unclear how healthy individuals would react to taking PB during the Gulf War deployment. There are instances where a drug administered to healthy people can cause more problems than when administered to those who are ill (for example, insulin injections help diabetics but can harm healthy people). However, FDA reviewed DOD’s proposed use of PB and had few concerns about PB’s potential toxicity because of its longstanding use to treat myasthenia gravis. FDA also expected that a healthy military population would experience even fewer side effects from PB than persons with that illness. In reaching this conclusion, FDA also reviewed data from DOD studies that evaluated PB’s usefulness and safety, although the number of persons in each study was small (usually less than ten), less than 100 persons were studied in all, and the studies excluded women and persons with certain diseases, such as asthmatics.¹⁹⁸

DOD APPLIED TO FDA TO USE INVESTIGATIONAL NEW DRUGS WITHOUT INFORMED CONSENT DURING THE GULF WAR

In planning for the Gulf War, DOD applied to FDA to use the botulinum toxoid vaccine and PB as INDs without obtaining informed consent from troops. DOD did this although “under the [sic] DOD directive the Secretary of the Military Departments can dictate the use of unapproved FDA regulated products.”¹⁹⁹ This application also was made despite the fact that IND products exported from the U.S. and used overseas do not need to meet investigational new drug regulations, and in particular “informed consent and investigational labeling are not required” in such circumstances.²⁰⁰ The FDA requires that the use of INDs be closely monitored, that accurate health records regarding their use be maintained, and that persons who receive these products give their informed consent before it is administered to them.²⁰¹

FDA and DOD both believed that the products discussed represented the best preventive or therapeutic treatment to provide protection against possible chemical and biological weapons.²⁰² FDA also gave “considerable deference to the Department of Defense’s judgement and expertise regarding the feasibility of obtaining informed consent under battlefield conditions.”²⁰³ However, major issues triggered by DOD’s request to use INDs without informed consent were the feasibility of requiring informed consent in a wartime context, product labeling, and interpretation of the 1987 memorandum of understanding on INDs.²⁰⁴ In particular, DOD did not want individuals to have an option of refusing to receive an IND product because that choice could result in the individual’s unnecessary death and could also jeopardize the lives of other soldiers who relied on that individual in a combat situation.

Prior to the Gulf War, FDA did not have a regulation that allowed INDs to be administered without informed consent to mentally competent individuals. DOD requested that FDA develop a new regulation that would allow this to occur. DOD stated in an October 30, 1990, letter to FDA, that:

“[f]or products that will be in the best interests of the patients, military combat exigencies may justify deeming it not feasible to obtain informed consent. FDA’s regulation should provide the mechanism, subject to appropriate limitations, for DOD to request on a drug-by-drug basis, and the Commissioner [of FDA] to decide, that a waiver be granted in cases in which it is established that military combat exigencies make that necessary.”²⁰⁵

FDA ISSUES AN INTERIM FINAL RULE THAT ALLOWS DOD TO USE PB AND BOTULINUM TOXOID VACCINE UNDER CERTAIN CONDITIONS WITHOUT INFORMED CONSENT

On December 21, 1990, FDA published an interim final rule that allowed FDA to waive informed consent on a case-by-case basis if three conditions were met. These conditions were:

- “1) the use was required to facilitate the accomplishment of the military mission;
- 2) the use would preserve the health of the individuals and the safety of other personnel, without regard for any individual’s preference for alternative treatment or no treatment; and
- 3) the application contained documentation to indicate that the protocol had been reviewed and approved by a duly constituted institutional review board for the use of the investigational new drug without informed consent.”²⁰⁶

FDA published this regulation within two months of DOD’s written request to FDA. However, by the time this interim final rule was published, troops had already been in theater for some months. On December 31, 1990, DOD asked that FDA allow the use of PB without informed consent and FDA approved this request on January 8, 1991.²⁰⁷ However, for the botulinum toxoid vaccine, the SIU could not find a record of a similar request by DOD to waive informed consent requirements for its use. FDA has also questioned whether DOD fully met those requirements.²⁰⁸

Although FDA agreed to waive informed consent requirements, FDA imposed other conditions on DOD’s use of IND products during the Gulf War. For the botulinum toxoid vaccine, FDA required that DOD record each vaccination on the individual’s permanent immunization record and maintain a roster with detailed information to identify all individuals receiving each vaccine dose. Adverse reactions were to be reported and a post-vaccination survey of a sample of individuals was to be done.²⁰⁹ DOD did not fulfill these requirements. For PB, DOD agreed to “collect, and summarize, adverse reaction data from medical personnel caring for casualties by the use of a form designed for this purpose, which the Agency found to be acceptable.”²¹⁰ In addition, DOD was to “provide and disseminate additional information to all military personnel concerning the risks and benefits of pyridostigmine,”²¹¹ and to label the packets that contained PB as “FOR MILITARY USE AND EVALUATION ONLY.”²¹² However, because packets containing PB tablets had been in the Gulf War theater since August 1990,²¹³ it appears that DOD’s agreement to label PB packages was made with the knowledge that it probably could not fully comply with this requirement.

HEALTH ISSUES DURING DEPLOYMENT

BACKGROUND ON DEPLOYED TROOPS

In evaluating the health status of those deployed during the Gulf War, that group’s characteristics are relevant in identifying whether particular health issues are of the type that normally would be expected to occur. From August 2, 1990, through July 31, 1991, 696,530 service personnel were deployed to the Gulf War theater of operations.²¹⁴ As shown in Table 1, the vast majority of deployed troops were enlisted males. Their median age was 24 years, although 28 percent were older than 30 years of age. Seven percent of deployed troops were women and the number of women who served in forward combat support positions was proportionately higher in comparison with previous

military deployments.²¹⁵ Almost one-fifth of those deployed were reservists, representing the largest mobilization and deployment of reserve component forces since the Korean War.²¹⁶ However, reserve troops reportedly received little or no health screening prior to deployment, unlike active duty troops who had access to the routine physical examination procedures that are part of the military's health care system.²¹⁷

Table 1. Characteristics of United States Military Servicemembers in the Gulf War (GW) Theater of Operations, August 2, 1990–July 31, 1991.²¹⁸

Characteristics	% GW Servicemembers (n= 696,530)
Male gender	93
Race	
White	70
Black	23
Hispanic	5
Other/Unknown	2
Median age	24 years
Age categories (years)	
17-20	11
21-25	38
26-30	22
31-35	13
36-65	15
Rank	
Enlisted	89
Officer	10
Other/unknown	1
Branch	
Air Force	12
Army	50
Marines	15
Navy	23
Status	
Active	83
Reserve component	17

MEDICAL FORCE BUILD-UP AND DEPLOYMENT FOR OPERATIONS DESERT SHIELD/STORM

In testimony before the Senate Committee on Veterans' Affairs, CENTCOM Commander General Norman Schwarzkopf (Ret.) described Operations Desert Shield/Storm as requiring "the largest medical mobilization that has taken place since World War II."²¹⁹ A key aspect of the medical mobilization was ensuring that an adequate number of in-theater hospital beds would be available to handle potential casualties, in addition to the hospital beds needed for possible medical evacuation to Europe and the United States. During Operation Desert Shield, the CENTCOM Surgeon General established an initial requirement for 7,350 hospital beds in-theater, which was later more than doubled to 18,530 beds. However, as of the beginning of the air campaign in January of 1991 this requirement had not been met. In the theater of operations, only about one-third (6,160) of the required beds were "operational"—meaning all personnel and equipment were in place and ready. Another 7,680 beds were "fully staffed", meaning that support personnel but not all required equipment was available for use. Overall, the in-theater health care system included 41,000 medical personnel and 65 hospitals, which consisted of two Navy ships, three Navy fleet hospitals, 44 Army hospitals, and 16 Air Force hospitals.²²⁰

OTHER IN-THEATER MILITARY MEDICAL PREPARATIONS

In addition to ensuring that basic medical support like hospital beds were available in theater, medical planning was also underway to prepare for and protect against a variety of health threats that troops were likely to encounter, such as chemical and biological weapons, and local environmental conditions or diseases. In his January 1997 testimony before the Senate Committee on Veterans' Affairs, General Schwarzkopf stated that DOD had predicted that U.S. forces would lose as many as 20,000 people if biological or chemical weapons were used by Iraq.²²¹ However, it has been suggested that the focus on the potential for Iraq's use of chemical and biological weapons may have resulted in a neglect of other fundamental preventive health practices such as comprehensive techniques for tracking potential toxic exposures and troop health status. Nevertheless, DOD health officials did develop and implement policies and plans to provide preventive medicine appropriate to the desert environment and to counter the threat of conventional and chemical or biological warfare. These included "preventive and environmental medicine, veterinary medicine, food inspection, medical and dental care, medical maintenance, supply and logistical support, and the movement and evacuation of patients."²²²

MEDICAL FORCE CAPABILITIES AND SHORTCOMINGS

Despite these preparations and plans, there were serious shortcomings in the medical force aspects of the Gulf War deployment. These shortcomings were such that, had the war lasted longer or had chemical or biological weapons been used by Iraq, the level of medical support available would have been unable to adequately respond to the casualties that would almost certainly have occurred. Despite the pre-conflict estimate of 20,000 in casualties if chemical or biological weapons was used

that General Schwarzkopf cited in his Senate testimony, DOD acknowledged in 1992 that it was not adequately prepared to deal with such casualties. For example, DOD admitted to only limited availability of important treatment resources such as drugs and antibiotics as well as “protection, detection, decontamination” and other therapies designed especially for BW and CW injuries.²²³ Moreover, of the three service branches, only the Army had protective shelter systems to be used for decontamination and medical treatment of chemical weapon casualties, and not all health-care staff had received comprehensive pre-deployment training for handling such casualties.²²⁴ Other problems arose due to inadequate training of active duty and reserve medical personnel as well as ground transportation problems that limited mobility of medical support to the front lines of battle.²²⁵ Even more troubling are the more detailed assessments in three studies performed by GAO of the medical readiness and capabilities of each branch of the military. GAO’s evaluations, summarized below for each service, demonstrate the degree to which the medical aspects of the Gulf War deployment fell far short of the level that would have been required to provide adequate care to injured troops had U.S. forces suffered the number of casualties that initially had been predicted.²²⁶

Shortcomings in Army Medical Capabilities

In reviewing the Army’s medical capabilities, GAO identified numerous significant problems before and during the ground war. For example, the system used to identify active duty medical personnel was incomplete and outdated, hindering efforts to deploy an adequate number of medical units. Moreover, many health professionals in reserve or National Guard units could not be deployed. Some did not meet physical fitness requirements; some had not kept current in their medical specialty or did not have complete medical training; some had not taken basic training. Many units had not trained adequately to familiarize medical personnel with unit missions and equipment.²²⁷ Many medical personnel also were unfamiliar with management and treatment of chemical warfare casualties, so initial training had to be done in-theater. Medical supply shortages occurred throughout the war and some hospitals were never fully equipped. Transportation and communication difficulties limited the ability to rapidly evacuate casualties from the battlefield or to communicate essential data on casualty status. Based on these shortfalls, GAO recommended that “the Secretary of the Army ensure that the doctrine involving the employment and configuration of battlefield hospital units is consistent with the battlefield of the future and that these units are sufficiently resourced with transportation and support assets to accomplish their missions”²²⁸

Shortcomings in Navy Medical Capabilities

Although the Navy rapidly deployed significant medical capabilities to the Gulf, GAO found that it was given missions by CENTCOM that it was not designed, staffed, or equipped to perform.²²⁹ Plans for transporting casualties to hospital ships did not take into account limited helicopter capabilities and travel times necessary to reach hospital ships. Crucial equipment and supplies would have been rapidly exhausted if casualty rates had approached estimated levels. The Navy’s medical capabilities for dealing with chemical warfare agents were severely limited. Fleet hospitals built

makeshift decontamination stations and improvised wash-down systems for airborne contaminants like chemical agents. With no reliable systems to remove contamination from those systems, the spread of contamination through that water or through decontamination exhaust vents located near air intake vents were also significant risks. Finally, as was true in the Army, only a small percentage of the Navy physicians deployed were trained to treat chemically contaminated casualties.²³⁰ GAO recommended that “the Secretary of the Navy set and enforce time frames to correct the shortcomings identified from lessons learned about medical operations during Operations Desert Shield and Desert Storm.”²³¹

Shortcomings in Air Force Medical Capabilities

Many of the same problems and shortcomings found in the Navy and Army medical capabilities were also true of the Air Force. Mission assignments to the Air Force far exceeded unit capabilities, resources, and expertise. Air Force medical units had supply and equipment problems and many of the medical personnel were inadequately trained. An Air Force after-action report stated that the estimated flow of casualties would have overwhelmed the system because not enough aircraft were allocated to evacuate patients. Even with adequate equipment, the report noted that it is very likely that there still would have been problems as there were shortfalls in the crews and in-flight evacuation equipment.²³²

THE LINK BETWEEN POTENTIAL EXPOSURES TO HARMFUL AGENTS AND ADVERSE HEALTH EFFECTS

Background

During the Gulf War, troops were exposed to many toxic agents that may have adversely affected their health either at the time of or after that deployment. In understanding the roles that these agents may have played in the illnesses that some Gulf War veterans now experience, some basic scientific concepts about the link between exposure and health effects are relevant. First, the simple fact an individual has been exposed to agents known to cause disease (whether infectious organisms or toxic chemicals) does not automatically result in that individual becoming ill. Illness occurs only after exposure to an amount of a harmful agent sufficient to trigger that illness. In addition, the amount of agent to which an individual is exposed does not stay static. For example, the human body frequently rids itself of harmful agents to which it has been exposed through normal bodily functions, including attacks by the body’s immune system.

Duration of exposure also can be an important factor in determining whether an agent has caused illness, so that a one-time exposure to a certain amount of an agent may cause adverse health effects but exposure to that same amount spread over a long period may not. Moreover, illness in an individual may not occur until long after an exposure. For example, exposure to large doses of radiation can rapidly cause death but exposure to low levels of radiation may cause cancer only many

years later.²³³ Also, some agents may interact in the body to jointly create a harmful effect. Therefore, in tracing the source of an illness it may be important to know if there were simultaneous exposures.²³⁴ Finally, everyone is exposed to multiple agents during the course of daily life that at certain levels can cause adverse health effects. Thus, in attempting to draw a causal link between known exposures to particular agents and illnesses that have occurred after those exposures, it is necessary to have reliable data to characterize exposures that normally occur as a part of daily life.

Measuring Exposure

The various ways in which exposure to certain substances or agents can, but may not always, cause illness in part demonstrates why it has been so difficult to determine why Gulf War veterans are ill. A link between exposure to an agent and illness is easier to draw if the agent is found still present in the body. Determining exposure to infectious agents like bacteria or viruses usually is based on identifying either the agent itself or antibodies against it. Determining exposure to chemical agents is usually done by measuring the amount of chemical in a person's body. Unfortunately, for many chemicals—including chemical weapons agents—this measurement cannot be done because effective laboratory tests do not yet exist.²³⁵ When actual measurement of exposure levels is not possible, scientists try to estimate the type and amount of a chemical that entered a person's body and determine if it was sufficient to cause health problems. Such after-the-fact exposure inquiries are only as good as the data on which they are based and do not account for differences in individual vulnerability to illness among those exposed.

Summary of Potential Troop Exposures to Harmful Agents During the Gulf War

During the years since the Gulf War, many agents have been suggested as possible sources of troop exposure and, in turn, as potential causes of the unexplained illnesses among Gulf War veterans. To review these potential causes in light of current available data, the SIU worked with the Department of Defense's United States Army Center for Health Promotion and Preventive Medicine (USACHPPM), which has overseen environmental monitoring for the Gulf War and Bosnia deployments. Using data provided by USACHPPM, which is set out in Figures 4 and 5, described below are the possible exposures to potentially harmful agents that some Gulf War veterans may have experienced. These figures are only guidelines for possible exposure. For example, individual service personnel may have been in-theater when an exposure was present and not have been exposed. Also described are some health effects due to these agents that could have occurred shortly following exposure. The SIU also asked several scientific experts to independently evaluate aspects of the possible long-term health consequences associated with these exposures. Chapter Four contains the full text or a summary of their reports, and the full text of the summarized reports is reproduced in the Appendix.

Biological Warfare Agents

Biological warfare (BW) agents are either live entities, such as bacteria and viruses, or they can be toxins or proteins produced by these entities.²³⁶ To be effective on the battlefield most BW agents must be dispersed in the air via mechanisms such as bombs, missiles, or spray tanks. Exposure to these agents would most likely occur by breathing them into the lungs. Following exposure to BW agents, persons develop diseases very similar to those that would occur following naturally acquired infection from such organisms.²³⁷ During the Gulf War, BW agent field detectors were relatively primitive and could not be relied upon to accurately detect exposure in a timely fashion.²³⁸ However, BW agents were likely not used because there is no intelligence evidence to date that indicates their use. In addition, the use of BW agents would have caused specific patterns of unique diseases that would have been noted by military physicians.

Finding: Any exposure of Gulf War veterans to BW weapons appears to be unlikely based on the information available at this time.

Figure 4. Total PGW Deployed Military Population and Potential Exposures

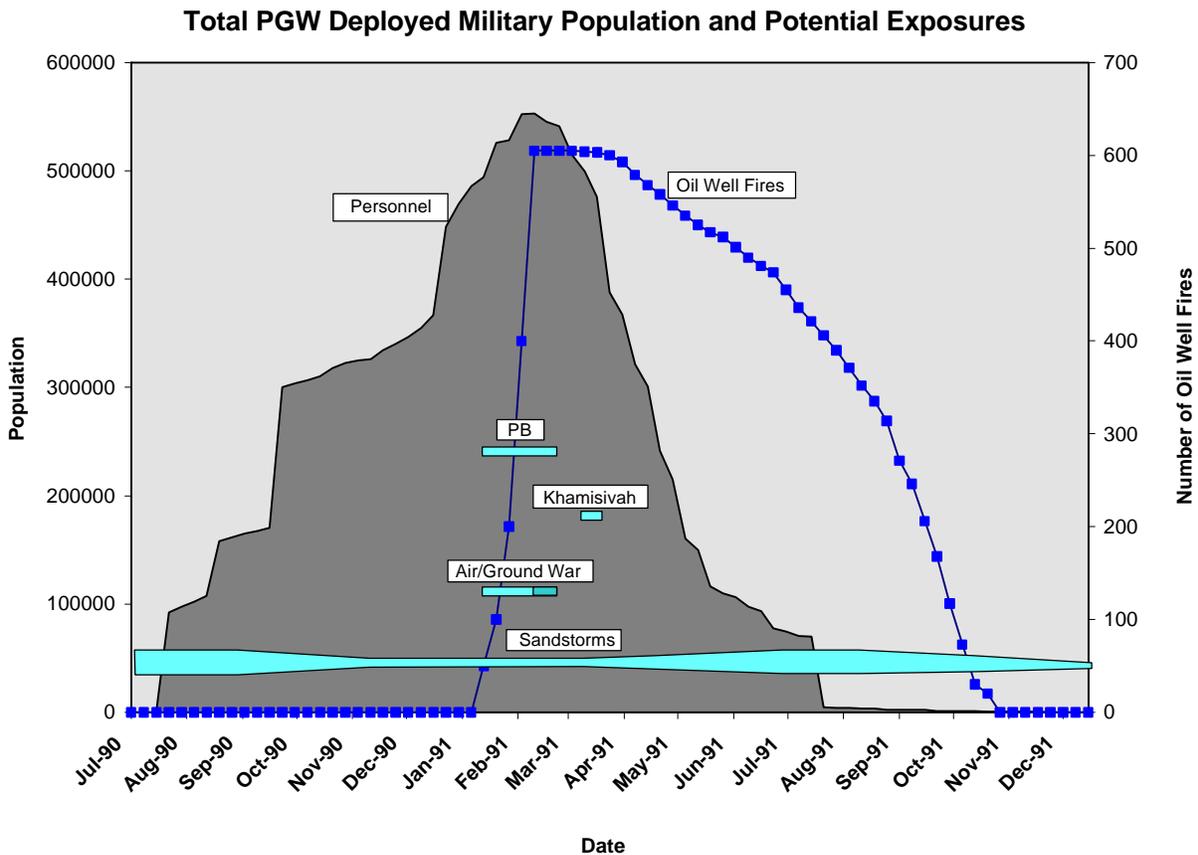
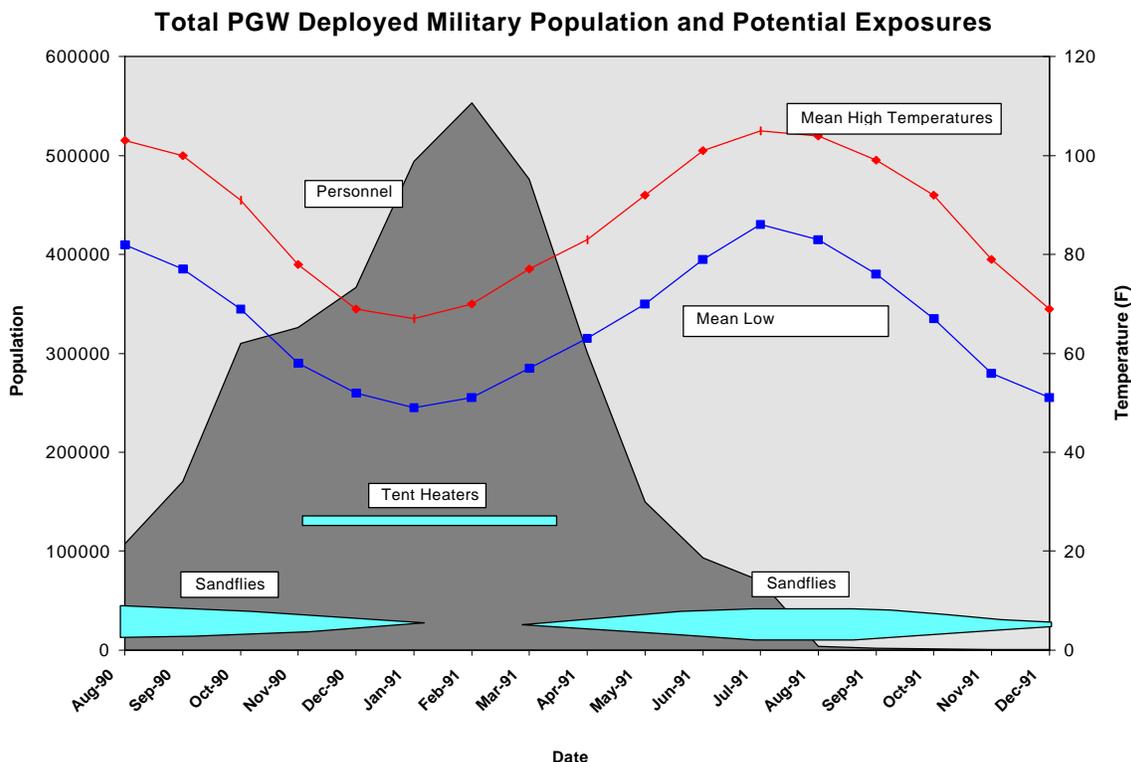


Figure 5: Total PGW Deployed Military Population and Potential Exposures—Continued



theater were from U.S. Air Force Environmental Technical Center data and the oil well fire data is from the National Oceanic and Atmospheric Administrations' Arabian Gulf Program Office. The sandstorm graphic was based on historical data and meteorological conditions and is not specific to the 1991 period. The sandfly data was provided to USACHPPM by Dr. William Reeves of the U.S. Centers for Disease Control and Prevention (CDC).

War

Chemical Warfare (CW) Agents

In the Gulf War, Iraq was assumed to have available included a variety of chemical warfare agents. Chemical warfare agents include mustard liquid (a blister agent), and nerve agents such as sarin (GB), soman (GD), tabun (GA), and VX. Mustard agent affects the skin and mucous membranes that it touches by forming blisters within twelve to 24 hours. Mustard can remain potent in its liquid form up to one hundred hours after release,²³⁹ but in a desert environment it can also evaporate quickly, producing a vapor affecting the lungs of those who breathe it in.²⁴⁰ Nerve agents inhibit an enzyme—acetylcholinesterase—in the nervous system. Exposure to nerve agents can cause nausea, vomiting, increased respiratory secretions, pinpoint size pupils in the eyes (miosis), convulsions, and respiratory failure resulting in death.²⁴¹ Some nerve agents can last for long periods of time in the environment (e.g., VX), while others dissipate rapidly (e.g., sarin and soman).²⁴²

There are no medical reports of symptoms or injuries to Gulf War troops consistent with acute exposure to CW agent. Although many medical records are incomplete or absent, exposure to CW agents in sufficient quantities to cause acute effects would likely have been noted, at least in medical reports to unit commanders. One report of exposure to a weaponized mustard agent during the Gulf War has been confirmed by DOD, most comprehensively in a case narrative issued by DOD/OASGWI. As discussed in Chapter One, that case narrative states that while performing reconnaissance in an Iraqi bunker on March 1, 1991, PFC David Fisher was likely exposed to mustard liquid. Eight hours after exploring the bunker, he developed burn signs and symptoms medically consistent with blister agent. FOX vehicle testing of liquid on Fisher's jacket was positive for a mustard agent on two separate readings. An initial urinalysis also indicated the presence of mustard agent. Although PFC Fisher received a Purple Heart for his injuries, later analysis of physical evidence was deemed inconclusive by DOD.²⁴³

Potential troop exposure to low levels of chemical agent that did not result in immediate symptoms or death cannot be assessed. As discussed in Chapter One regarding DOD/CIA attempts to produce computer models of the Khamisiyah incident (the only CW release during the Gulf War according to currently available information), there is no contemporaneous data to verify the presence or absence of such agents in-theater nor to determine the extent of possible troop exposure.

Finding: With the exception of PFC Fisher's injuries, there are currently no other reports of injuries consistent with exposure to chemical weapons agents sufficient to cause immediate significant or life-threatening symptoms. However, exposures to low levels of chemical agents could not be assessed as DOD lacked reliable detection methods for low level exposures.

Depleted Uranium

DOD uses depleted uranium (DU), a very dense metal, to increase the penetration capability of certain munitions and as a protective shield on tanks against enemy fire. DU is a byproduct in uranium refinement and its radioactivity is about half that of natural uranium.²⁴⁴ DU was first used in combat during the Gulf War, during which U.S. troops collectively fired approximately 285 tons of DU munitions.²⁴⁵ Many U.S. troops handled munitions containing DU, but because the DU is encased in a protective shell, that type of contact alone is unlikely to have resulted in exposure. However, during the Gulf War, troop exposure to DU occurred in other ways. Thirty-six persons were wounded with DU shrapnel in friendly-fire incidents.²⁴⁶ Of these, 33 currently are being followed medically and 15 still have detectable shrapnel fragments in their bodies.²⁴⁷ Additionally, unknown numbers of troops may have inhaled particles containing DU while working near a fire at the Doha, Kuwait, armored vehicle depot, or while climbing onto allied or enemy vehicles that had been hit by munitions containing DU.²⁴⁸ Gulf War veterans told SIU investigators that DOD provided little or no information and training that described potential health risks from contact with exploded DU munitions or how to minimize exposure to DU in such situations. This is consistent

with GAO findings and has been acknowledged by DOD as an area in which improvement is needed.²⁴⁹

Acute and long-term health effects from DU exposure mostly likely stem from the toxicity of its heavy metal properties rather than radioactivity.²⁵⁰ Symptoms of acute exposure are irritated eyes or upper respiratory tract problems.²⁵¹ These health complaints were reported nearly three times as often by troops in the Gulf War theater than by a comparable military group stationed in the U.S. (19 percent versus 7 percent of those troops).²⁵² However, it is unclear whether these complaints stemmed from exposure to DU or exposure to other factors such as sand or respiratory viruses. Although DU's radiation cannot penetrate the skin,²⁵³ inhaled or ingested DU may cause lung or kidney damage.²⁵⁴ However, there are no reports of acute, symptomatic lung or kidney damage during the Gulf War deployment that required unique intensive medical care for such symptoms, such as dialysis.

Finding: In addition to troops who were wounded by DU shrapnel, an unknown number of troops were exposed to low levels of DU, probably by inhaling DU particles.

Heat

Because the Gulf War deployment occurred in a desert setting, U.S. service members experienced certain health exposures characteristic of that environment. In the initial months of the deployment, troops were exposed to summer daytime temperatures that reached as high as 130 degrees Fahrenheit (F).²⁵⁵ In August and September, mean high temperatures were approximately 100 degrees F, with very intense solar heat and low humidity (see Figure 4). During the Gulf War, the U.S. military was well aware that the desert environment could contribute to heat stress and provided information to troops on fluid management and prevention of heat-related illnesses.²⁵⁶ There is insufficient data to determine how many troops had heat-related health problems. However, based on health surveillance data collected on approximately 40,000 Marines (about six percent of all deployed U.S. troops), less than three cases of heat injury requiring aid station treatment occurred weekly per 1,000 personnel under surveillance.²⁵⁷

Preliminary research by Israeli scientists suggests that heat stress can cause cerebral deficiency even in temperatures slightly above 100 degrees Fahrenheit.²⁵⁸ The Israeli military has reported that a few Israeli soldiers have developed undiagnosed illness-type symptoms (e.g., fatigue and memory problems) after symptomatic heat stress. More than 95 percent of those soldiers recovered fully and most did so in a matter of weeks, although some took up to a year.²⁵⁹

Finding: Based on available data as shown in Figure 5, many troops were exposed to conditions of extreme heat during part of the deployment.

Infectious Diseases

Many infectious diseases are prevalent in the Middle East including, but not limited to, agents causing diarrheal diseases, leishmania, sandfly fever, and malaria.²⁶⁰ The Navy's health surveillance system during the Gulf War that collected data on about six percent of all deployed troops found that, based on that group's data, the incidence of reported infectious diseases during the Gulf War was lower than during previous wars. Diarrhea was the most commonly reported condition, and up to four percent of those troops were ill per week. Cases of diarrhea decreased once troops no longer received locally obtained fresh produce with their meals, but outbreaks continued during deployment and were likely connected to living in crowded tents without indoor plumbing, eating in local restaurants, and food preparation by local hires.²⁶¹ As noted above, upper respiratory complaints were also common among Gulf War troops but it is unclear whether these problems were due to infectious organisms. (See the consultant report of Dr. Michael Lebowitz in Chapter Four and at Appendix KK.) Although unknown numbers of persons likely were infected with organisms that cause gastrointestinal and respiratory diseases, no troops are known to have developed sandfly fever. Seven persons developed malaria; one contracted West Nile fever; and one died from meningococcal meningitis.²⁶²

Leishmania—Leishmania is a parasitic disease transmitted by the bite of the adult sandfly, which also transmits sandfly fever.²⁶³ In the Middle East, Leishmania organisms typically cause either a skin disease (cutaneous disease) or disease of internal body organs such as the liver or spleen (visceral disease). There are neither blood nor skin tests for leishmania, thus, diagnosis is difficult and requires identification of the parasite in bone marrow samples.²⁶⁴ The adult sandfly that spreads the leishmania organism is inactive during the cooler, winter months (see figure 2).²⁶⁵ Thus, during the Gulf War most troops probably were at low risk of exposure to Leishmania organisms because they were in the area during the winter months when the sandfly is less likely to spread the disease. In addition, the widespread use of pesticides²⁶⁶ by DOD may have diminished the sandfly population in areas where troops lived. Since the end of the Gulf War, 32 persons have been diagnosed with leishmaniasis,²⁶⁷ with the last case diagnosed in 1993.²⁶⁸

A study conducted by the CDC has attempted to better understand exposure to the sandfly and illnesses among Gulf War veterans. CDC examined the blood of 154 Gulf War veterans who were in four units, and looked for evidence of exposure to sandfly fever, which is evidence of exposure to the sandfly. CDC found that about six percent of the veterans did show evidence of that exposure. However, there was no association between sandfly exposure and an individual's health status at the time of the study. In addition, among ill persons there was no association between exposure and the type or severity of reported symptoms such as fatigue, abdominal cramps, or skin rash. CDC concluded that among Gulf War veterans in those units exposure to the sandfly was not associated with illness.²⁶⁹

Mycoplasma—Mycoplasma organisms are bacteria that are found on healthy humans, animals and birds.²⁷⁰ Mycoplasma are also common contaminants of animal cell cultures, and some types of mycoplasma can cause disease in humans, such as pneumonia caused by *Mycoplasma pneumoniae*.²⁷¹ Some researchers have postulated that mycoplasma infection is a possible factor affecting the health of Gulf War veterans with undiagnosed illnesses, although the source of such exposure, if any, is not clear. In particular, the strain *Mycoplasma fermentans* has been proposed as contributing to these illnesses by affecting certain human immune responses. To assist this investigation, a national expert in the field of mycoplasma, Dr. Kevin Dybvig, prepared and submitted at the SIU's request a report providing an overview of mycoplasma in the context of Gulf War illnesses and a review of related scientific literature. That report can be found in Chapter Four.

At least one research effort into a potential link between *Mycoplasma fermentans* and Gulf War illnesses is currently underway. As of the writing of this report, the Department of Defense was in the process of providing approximately \$150,000 to molecular biologist Dr. Garth Nicolson of the Institute for Molecular Medicine. Dr. Nicolson and his colleagues claim that they have detected *Mycoplasma fermentans* in some ill Gulf War veterans using a particular laboratory technique that they developed. This DOD funding has been provided to enable Dr. Nicolson and his colleagues to teach their technique to laboratory teams from three facilities—one government laboratory and two universities. These laboratories are the Armed Forces Institute of Pathology; the University of Texas Health Science Center (San Antonio); and the University of California (Irvine). Once scientists are trained at the three laboratories, double blind testing of specimens will occur by all laboratory teams and Dr. Nicolson's laboratory to verify the validity and reproducibility of the new testing procedure. Research into a possible link between *Mycoplasma fermentans* and Gulf War illnesses is in preliminary stages, and the SIU is not in a position to reach any conclusions on this matter.

Finding: Many troops were likely infected with organisms that caused diarrhea and respiratory diseases during the Gulf War deployment. Thirty-two persons developed leishmania, and few service personnel developed malaria, West Nile fever, and meningococcal meningitis.

Oil Well Fires

Towards the end of the Gulf War in February 1991, more than six hundred Kuwaiti oil wells and refineries were set on fire by the Iraqi troops (see Figure 1).²⁷² Air monitoring for pollutants from these fires was done by several U.S. and international agencies. Environmental Protection Agency (EPA) personnel were in Kuwait beginning in March 1991 and the U.S. Army's Environmental Hygiene Agency collected samples from May through December 1991.²⁷³ However, there was limited data collected earlier when most of the troops were in the area. The fires released numerous air pollutants, including particulate matter, volatile organic compounds (VOCs), sulfur oxides, nitrogen oxides, vanadium, and nickel. CDC measured the amount of VOCs in some individuals shortly after the Gulf War and found high levels among firefighters, however, persons in Kuwait City had levels comparable to the general U.S. population.²⁷⁴

Acute health effects associated with exposure to oil well fires would include irritation of the respiratory system and the eyes, which as mentioned previously appeared to be more common among some Gulf War troops than some troops in the U.S. However, this increase may be attributed to other exposures such as sand or infectious agents. (See the consultant report of Dr. Lebowitz in Chapter Four and at Appendix KK.) Pulmonary function tests were completed on a limited number of persons and their results did not differ significantly from troops stationed in Germany.²⁷⁵ The Armed Forces Institute of Pathology also compared autopsy results of 149 Gulf War veterans who died before the fires started with autopsy results of 202 persons who died after the fires began and found no significant differences between them.²⁷⁶

Finding: Based on available data, unknown numbers of troops were likely exposed to high concentrations of particulate matter, metals, sulfur and nitrogen oxides in the air as a result of oil well fires.

Pesticides

The military used many types of pesticides, insecticides, and rodenticides during the Gulf War deployment to which many troops were exposed. These chemicals fell into five major categories: carbamate, organophosphorus, chlorinated hydrocarbon (lindane), pyrethroid pesticides, and others such as N,N-Diethyl-*m*-toluamide (DEET).²⁷⁷ (See the consultant reports of Drs. Frederic Gerr and Matthew Keifer in Chapter Four and at Appendix II and JJ.) Organophosphate and carbamate pesticides act similarly to chemical warfare agents by inhibiting the enzyme acetylcholinesterase in the nervous system and acute health effects from exposure to them also include muscle twitching, vomiting, diarrhea, and possible respiratory suppression and death. Exposure to pyrethroid pesticides can result in nausea, incoordination, and eye and skin irritation.²⁷⁸ Most pesticides and similar substances used during the Gulf War were obtained from the United States. At least one pesticide, "SNIP,"²⁷⁹ was purchased locally,²⁸⁰ and it is unclear whether other pesticides were also locally obtained. DOD officials advised SIU investigators that DOD may have used local contractors early in the deployment to spray the dormitory facilities of several military units with unknown pesticides. DOD could not confirm this.

Although DOD kept records describing the type and amount of pesticides shipped from the United States, no records documented how individual service personnel used these chemicals. For example, DOD has reported that troops each received an average of about 2.0 tubes of DEET (33% concentration) intended for use directly on the body and 2.2 spray-cans of premethrin for use on uniforms; however, no records reflect how these agents were actually used.²⁸¹ Most other pesticides such as those used to control insects in camps were used by troops who reportedly were trained to follow strict guidelines in their use. However, it is unknown how many troops understood and followed safe occupational health practices when using these agents.²⁸² In addition, some service personnel chose to wear animal flea collars to ward off insects although DOD discouraged this practice because the health effects of human use is unknown. Some troops reportedly developed

rashes as a consequence of their use.²⁸³ However, no other acute health effects have been linked to the use of pesticides during the Gulf War.²⁸⁴

Finding: Most troops were likely exposed to some level of a variety of these chemicals although the amount or level of exposure is not known.

Pyridostigmine Bromide

As discussed earlier in this chapter, DOD obtained approval from FDA to administer pyridostigmine bromide (PB) as a pretreatment to guard against ill effects from exposure to some types of chemical weapons agents. FDA's conditions for its approval were that DOD inform troops as to why they were receiving PB, and that DOD keep records of who took PB as well as any adverse health effects that occurred.²⁸⁵ During the Gulf War, PB was to be used at the commanding officer's judgement and was to be self-administered by individuals in 30 mg doses three times daily. DOD kept no records to document who took PB and how much was taken despite the FDA's requirement to do so. DOD believes that about 250,000 personnel took at least some PB during the deployment.²⁸⁶ However, in many instances some troops did not take PB despite their commanders' orders to do so and some troops took several doses all at once when they heard CW alarms sound, reasoning that if one tablet would protect them against CW agents several tablets would work even better.²⁸⁷

Excessive doses of PB will cause many of the same toxic effects that nerve agents do and the recommended dosage in the Gulf did in fact lead to "annoying side effects" in about half the troops in theater.²⁸⁸ For example, information collected from medical officers of the XVII Airborne Corps regarding the symptoms and disposition of 41,650 members of the Air Force who received PB beginning in January 1991 showed that over half the troops experienced gastrointestinal symptoms and up to one-third complained of urinary urgency. Other side effects included hypertension in two individuals, headaches in five, and breathing difficulties in one with a history of asthma. At least one soldier experienced an overdose after inadvertently taking two tablets. The researchers concluded that approximately one percent of the individuals reported side effects that were severe enough to warrant medical attention and fewer than one-tenth of a percent had side effects severe enough to discontinue the drug.²⁸⁹

For many years, scientists thought that PB did not enter the brain because the brain's protective layers (also known as the blood-brain barrier) prevented that. However, recent DOD-funded research has shown that when a rodent is placed in a stressful situation, the protective layers of their brain become permeable and PB does enter the brain.²⁹⁰ It is unknown whether the human blood-brain barrier reacts similarly in stressful situations (including combat) and, if so, for how long the permeability may last. It is reasonable to conclude that if the human blood-brain barrier does become permeable in stressful situations, the brains of some soldiers may have been exposed to PB. The health consequences of such exposure are unknown.²⁹¹ In addition, as is discussed later in this chapter regarding the health effects of multiple exposures, PB may also interact with pesticides and

potentially create adverse health effects at lower doses of these agents, although the health consequences of such multiple exposures are also unknown. (See the consultant reports of Dr. Keifer, found in Chapter Four and at Appendix JJ, and Dr. James Moss in Chapter Four.)

Finding: Pyridostigmine bromide tablets were taken by about 250,000 troops; PB was likely more commonly taken during the air and ground wars in 1991 (January 16-27 and February 24-28, respectively).

Sand

Air monitoring during the Gulf War deployment revealed very high concentrations of particles that could enter and irritate the respiratory system and possibly cause low-grade lung inflammation.²⁹² Some particles were the result of oil-well fires but much was likely due to sand.²⁹³ Respiratory system irritation by airborne particles may compromise that system's ability to ward off other agents, including viruses. Of one group of U.S. troops under medical surveillance, a high rate of respiratory illnesses occurred at the beginning of the deployment, which later declined and increased again during the winter months.²⁹⁴ Long-term health consequences of inhaled exposure to fine sand particles, if any, are unknown. Some researchers have suggested that fine sand dust in combination with pigeon droppings in Saudi Arabian cities could have triggered an immune reaction that caused low-grade lung inflammation, and found that ill individuals in their study suffered a variety of complaints during the Gulf War that included nasal congestion, fever, sore throat, and generalized malaise.²⁹⁵ However, abnormal lung findings in this group were rare and most persons recovered from their symptoms after about three weeks.²⁹⁶ The long term health effects, if any, are unknown.

Finding: Most troops in theater were probably exposed to sand of a size that could be inhaled (see Figure 4).

Solvents: Petroleum Products, Diesel Heaters, and Others

Solvents are liquids that usually become vapors at room temperature, dissolve many organic compounds, and commonly are used as fuels, carriers for paints, and thinners. (See the consultant report of Dr. Gerr found in Chapter Four and at Appendix JJ.) Throughout the Gulf War theater, a variety of petroleum products were used. About 145,000 gallons of gasoline were used per day for the eight months starting in August 1990.²⁹⁷ Besides use in vehicles and machine engines, petroleum products were also used to burn human waste as well as trash, and as fuel in stoves.²⁹⁸ Diesel fuel was used in large amounts to suppress dust, with one reported case involving 30,000 gallons used on roads daily.²⁹⁹ In addition, the Navy and Marine Corps (and perhaps the Army) used unvented heaters in tents that were fueled with gasoline and diesel fuels.³⁰⁰ In all of these uses, these solvents likely released benzene, xylene, carbon monoxide, particulates, lead, and sulfur, as well as nitrogen oxides into air that troops breathed.³⁰¹ In addition, Chemical Agent Resistant Coating (CARC) paint, which releases a compound (toluene diisocyanate) that can adversely affect the lungs, was applied

to vehicles and equipment before shipment to the Gulf area or at port in Dhahran. Some persons who applied CARC paint may have done so without appropriate protective measures, although reports indicate that only a limited number of Gulf War veterans were exposed to CARC.³⁰²

During the deployment, some individuals experienced acute adverse health effects attributable to solvents. Persons who applied diesel fuels for sand suppression developed nausea, as did those who lived in tents near those roads.³⁰³ Accidental exposure to a chemical decontaminant agent (DS2) reportedly caused rashes in a group of soldiers.³⁰⁴ However, CDC obtained blood samples from some troops and did not find higher levels of volatile organic compounds, a marker for exposure to some of these compounds, than the background U.S. levels.³⁰⁵

Finding: No records were kept, but many troops were exposed to solvents, including diesel fuel and by-products from kerosene space heaters in unvented tents (see Figure 5). Exposure levels in these circumstances intermittently could have been very high.

Stress

Much has already been written about stress and the Gulf War, but often with poor specificity as to how the term 'stress' is defined. (See the consultant report of Dr. Richard Letz in Chapter Four for additional discussion of this problem.) In this report, troop exposure to "stress" means a collection of extremely adverse or potentially traumatic conditions that U.S. military personnel faced during deployment to the Gulf War, rather than their adjustment to or reactions following these events. While the war consisted of less than 100 hours of open, direct combat, the brief nature of the actual conflict does not negate the stressfulness of the deployment and the conflict that followed.

Moreover in defining stressful exposures, it is important to avoid labeling events as "physically" versus "psychologically" stressful. Researchers examining the effects of trauma on health note that these distinctions are "neither useful nor realistic . . . because each may interact with the other and both undoubtedly contribute to the suffering and despair associated with traumatic exposure."³⁰⁶ In the last decade, health scientists have only recently begun to understand and measure biological responses to stress, as reflected in changes in hormonal, physiological, and immunological functioning. (For a more complete discussion of this issue, see the consultant report of Dr. Letz in Chapter Four.)

The Ft. Devens Operation Desert Shield/Storm Reunion study examined reported stressful wartime exposures in a group of over 2,000 Gulf War veterans as they returned home.³⁰⁷ In addition to listing traditional combat experiences as stressful, this group reported nearly 300 other events that they identified as stressful, although it was not possible to identify individual levels of exposure to particular events.³⁰⁸ Categories of reported stress-related events included: (a) combat/mission stressors (e.g., actual threat to life from missiles or direct exposure to another's death or injury as part of a combat mission); (b) noncombat, war-zone stressor (e.g., a unit member seriously injured or

killed in a non-mission accident); (c) domestic stressor (e.g., long separation from or illness of family members and loved ones; divorce); (d) anticipation of war/combat activities (e.g., from missile attack alerts or fear of BW/CW attack); (e) physical/situational attributes of the war zone (e.g., severe climate or environmental conditions; long tours of duty; uncertainty about the war's duration); and (f) intraunit personal 'hassles' (e.g., personal conflicts in a unit; leadership problems or failure; harassment).³⁰⁹

Some of these stressful events are of particular significance in the context of the Gulf War. For example, troop exposure to "friendly fire" incidents (the inadvertent firing by U.S. forces on other U.S. forces) were and are likely to continue be a source of uniquely traumatic combat exposure. DOD reported to Congress in 1992 that the same factors that made for coalition success during the Gulf War—its rapid pace, a less structured battlefield, and more lethal and sophisticated weapons systems—also increased the risk of friendly fire casualties.³¹⁰ There were 28 incidents of fire from friendly forces resulting in the deaths of 35 service personnel and the wounding of 72 others.³¹¹ As these same factors will likely continue to characterize modern military conflict, service members who experience such events should be monitored over time and the information from that monitoring used to design and implement effective military health interventions and debriefings in future deployments.

Also, the additional physical and psychological burdens on troops stemming from possible offensive use of BW or CW during the Gulf War have been identified by military health researchers as a potential future source of stress exposure greater than that of more traditional military conflicts.³¹² Aspects of this include physical limitations and dangers from wearing chemical protective gear in a desert environment³¹³ and moderate to severe reactions of anxiety, panic, and claustrophobia estimated to occur in 10 to 20 percent of troops in one study.³¹⁴ Finally, stress from personal and family concerns likely played a more prominent role in the Gulf War deployment because it involved a greater number of married personnel and parents. For example, only 16 percent of those deployed in the Vietnam War were married with children. In contrast, in the Gulf War 60 percent—almost two-thirds—of U.S. service members and reservists were married with dependents, including approximately 32,000 single parents who had to make arrangements for their children during the deployment.³¹⁵

Finding: It is highly likely that troops in-theater were exposed to a wide array of very stressful and traumatic events and conditions.

Vaccines

DOD routinely administers vaccines to troops. Each service branch has different vaccine requirements upon entry into service, when individuals are assigned to groups likely to be deployed overseas, when troops are deployed, and for others engaged in certain high-risk occupations in the military.³¹⁶ Vaccinations generally administered include cholera, hepatitis A and B, influenza,

Japanese B encephalitis, measles, polio, plague, rabies, rubella, tetanus-diphtheria, typhoid fever (*Salmonella typhi*), varicella, and yellow fever.³¹⁷ During the Gulf War, approximately 150,000 doses of anthrax and 8,000 doses of botulinum toxoid vaccine were administered by DOD to protect against potential Iraqi use of biological warfare agents.

Anthrax Vaccine—The anthrax vaccine has been licensed by FDA since 1970. It consists of a series of injections: three injections over six weeks followed by three more injections over 18 months and an annual booster thereafter. Mild reactions at the injection site, such as pain or swelling, occur in about 30 percent of vaccinated persons. Flu-like symptoms occur in fewer than 0.2 percent of those vaccinated.³¹⁸ DOD uses the vaccine to protect individuals from anthrax exposure of the skin, lungs, and digestive tract. The vaccine is judged approximately 93 percent effective against the development of anthrax of the skin,³¹⁹ but there is limited data as to its effectiveness in protecting against inhaled anthrax, which can occur if anthrax is used as a BW agent and released into the air. Animal studies have demonstrated the protective effect of the vaccine against inhaled anthrax,³²⁰ but animal models do not necessarily apply to humans and studies in which humans are deliberately exposed to anthrax are unethical to perform. One study conducted in the 1960s followed 1,200 persons who were at risk of developing anthrax at their jobs (in this case, using imported goat hair to manufacture fabric).³²¹ The anthrax vaccine, not yet licensed at the time, was provided to some of these workers and all were followed to determine if the vaccine appeared to provide protection from anthrax. Five cases of anthrax through inhalation, four of which were fatal, occurred among the unvaccinated group; none occurred among those who were vaccinated.³²² CDC data on occupational anthrax cases in the United States from 1961 through 1974 identified 27 inhalation cases; none occurred among fully vaccinated persons but three cases occurred among persons not completing the full inoculation series.³²³ This data suggests that the vaccine can protect humans against inhaled anthrax but to date there is inadequate information to judge how well it works, particularly against weaponized anthrax, which could cause exposure to greater concentrations of anthrax than has occurred among workers exposed on the job.

Botulinum Toxoid Vaccine—The botulinum toxoid vaccine is not a fully FDA licensed product but, as discussed earlier in this chapter, as an IND it is administered to humans provided they give informed consent. Used for nearly thirty years to immunize laboratory workers and other persons at risk of the disease, 10,414 doses were administered from 1970 through 1990. Three doses are administered over a three month period and a booster is required one year after the first dose³²⁴ Side effects included pain, redness, and swelling at the injection site.³²⁵ These symptoms occur in less than six percent of those receiving the initial three doses and about ten percent of persons receiving the booster. A few individuals (about 0.4 percent) have general flu-like symptoms and are unable to perform their duties for one to two days. The vaccine's ability to protect against respiratory exposure, such as might occur if botulinum toxoid was used as a biological warfare agent and released into the air, is unknown.³²⁶

Inadequate Record Keeping of Vaccine Administration During the Gulf War—During the Gulf War, DOD failed to keep adequate records to document which troops received the anthrax and botulinum toxoid vaccines. Nor did DOD comply with its agreement with FDA to keep detailed records on those receiving the botulinum toxoid vaccine as a condition for its use without obtaining informed consent from Gulf War troops. This lack of record keeping occurred despite FDA’s modification of its initial record keeping requirements to accommodate DOD’s explanation of limits to its ability to collect data during wartime. For example, FDA continued to require that DOD report unexpected life-threatening events connected with the use of the vaccine but permitted DOD to report these events “in as timely a manner as conditions permit” in lieu of requiring reports by phone within three days.³²⁷ DOD has defended its failure to note vaccine information on service members’ permanent immunization records by claiming that information on which units received the vaccine was classified.³²⁸ In a July 1997 letter to DOD on this matter, FDA also noted that the number of botulinum toxoid vaccine doses DOD indicated it administered (8,000) and the number it returned “does not total the number of doses shipped.” According to FDA’s letter, DOD justified this discrepancy by stating that its “records of vaccine destruction were not maintained because its use occurred in a war zone.”³²⁹

Squalene—A recent theory has emerged that some of the vaccines administered during the Gulf War contained squalene and that this may have been associated with the chronic, debilitating illnesses that have occurred among some veterans. Squalene is a natural, organic compound that is found in some oils, such as olive oil, and in the human body as a compound used in making cholesterol.³³⁰ According to FDA, squalene can be contained in a vaccine due to two different processes. It can occur as an adjuvant, which is an agent to enhance the immune response. FDA has stated to SIU investigators that none of the vaccines used during the Gulf War contained squalene as an adjuvant and the SIU has seen no credible evidence to the contrary. Additionally, extremely minute quantities of squalene could be found in vaccines manufactured using eggs, since eggs are rich in squalene and cholesterol. This type of manufacturing would affect vaccines in general, and not just vaccines administered to Gulf War veterans. As of the writing of this report, there is no peer reviewed literature that comments on the health effects of such exposure to squalene.³³¹

Potential Health Effects of Simultaneous Administration of Multiple Vaccines—Some have suggested that Gulf War veterans who received more than one vaccine at the same time are at increased risk of developing illnesses because their immune systems were somehow adversely affected by this vaccination process. This interesting theory would not only possibly affect veterans but also many children and adults who receive multiple vaccines simultaneously as part of routine, preventive health care. Additionally, in the course of life, the human body is exposed to many foreign agents simultaneously, as for example when numerous agents enter the body through a cut or scrape on the skin. Although it appears unlikely that simultaneous receipt of multiple vaccines contributed to Gulf War illnesses, there is insufficient data to appropriately evaluate this issue.

Finding: About 150,000 persons may have received at least one dose of anthrax vaccine and about 8,000 may have received one dose of the botulinum toxoid vaccine.

EFFECT OF MULTIPLE EXPOSURES ON GULF WAR VETERANS' HEALTH

Detailed records do not exist to describe the type and level of exposures that individual Gulf War veterans experienced that may have resulted in adverse health effects. However, it is clear that at least some troops deployed to the Gulf War were simultaneously exposed to many of these substances or agents. Science is only beginning to develop methods to better understand the interactive effects of many agents, and researchers are devoting time and effort to better clarify the health effects of such interactions. Recent research has demonstrated that some of the exposures that Gulf War veterans likely experienced can work together to cause adverse health effects at lower doses than would individual exposures to those agents. One example is recent research on the interaction between PB and some pesticides,³³² which is discussed in more detail in consultant reports found in Chapter Four and in the Appendix. Another potential interaction of possible concern is that of PB and exposure to heat. DOD documentation notes that because PB decreases the heart rate and increases sweating, it may interfere with troop ability to perform heavy workloads at high temperatures.³³³ Because so little is now known about the health effects of multiple environmental exposures, this area is one especially ripe for ongoing research.

POOR DATA COLLECTION ON GULF WAR EXPOSURES HINDERS CURRENT TREATMENT AND RESEARCH EFFORTS

Whether conducting research on Gulf War veterans as a whole or treating individual veterans, it is not enough simply to know that at least some of those troops likely were exposed to many potentially harmful agents during deployment. Especially when treating individual Gulf War veterans with unexplained symptoms, it is critical to know with some degree of certainty the type and level of that veteran's exposures to determine whether they contributed to his or her illness. Individual service personnel exposure levels could be identified in two basic ways. One method would ask the ill veteran to describe his or her exposures. However, gathering exposure data through a self-reporting method has several flaws, including that not every veteran would know or recognize many pertinent details related to certain exposures nor is it likely that accurate details would be remembered after the fact, especially some years later.³³⁴ Another method is to ensure that accurate written records of exposure are kept during a deployment so that they are available if needed in the future. For example, records could either document an exposure, such as the receipt of a vaccine, or troop physical location near certain exposures, such as being near oil-well fires.

During the Gulf War, however, almost no written records were kept describing exposure to any agent.³³⁵ DOD did compile several lists of toxic compounds such as pesticides that were used during the deployment,³³⁶ but there is no accurate data on how they were used or who came in contact with them and at what levels. Although much data exists quantifying air pollutant exposure from burning

oil fires, it was primarily collected after most troops had returned to the United States. Moreover, the morning reports kept during previous wars were not produced during the Gulf War. These reports could have helped provide data on the daily location of individual service members that cannot be recreated. DOD now attempts to keep such exposure-related records in the current Bosnia deployment as part of a comprehensive process that also attempts to quantify exposure by collecting environmental measurements and samples of blood and urine.³³⁷ These efforts should be evaluated to judge their completeness and effectiveness. During future deployments, troop exposure to chemical toxicants could be better evaluated if laboratory methods were developed to rapidly screen people for the presence of toxic chemicals. CDC has indicated it could develop the laboratory diagnostic capabilities to rapidly detect 150 toxic substances (including chemical warfare agents) in people. The SIU encourages DOD to provide CDC with sufficient funds to develop this capability.

POOR TRACKING OF GULF WAR HEALTH STATUS HINDERS CURRENT TREATMENT AND RESEARCH EFFORTS

In addition to exposure-related data that could have been but was not collected during the Gulf War, another tool that would be useful in treating and researching Gulf War veterans would be data on the health status of deployed troops before, during, and after their deployment. Standardized pre- and post-deployment physical examinations, including blood work, could provide baseline information to determine exactly how the health of veterans changed during or subsequent to the conflict. However, physical examinations were “not routinely provided to all members of the military, nor were they provided to many Guard and Reserve members called up for the Persian Gulf War.”³³⁸ Most health-related data that would be a rich source of information on adverse health effects during deployment was either not collected or lost. Such information could have helped determine the extent and frequency of particular symptoms or diseases and might have provided clues as to exposures that may have contributed to them. Many in-theater hospitalization records do not exist, and according to DOD were lost or possibly burned.³³⁹ However, DOD recently revealed that some in-theater hospitalization records long thought to be lost have been found at the National Personnel Records Center located in St. Louis.³⁴⁰ These records could be useful in providing information about the types of health problems that resulted in hospitalizations during the deployment. DOD is currently planning to inventory these records, produce an index, and notify veterans whose records are identified.

Improved Medical Surveillance during the Gulf War Could Have Collected Important Health Information

In a medical context, surveillance is the ongoing and systematic collection, analysis, and interpretation of health data used in describing and monitoring a health event in order to plan, implement, and evaluate health interventions and programs.³⁴¹ As previously mentioned in this Chapter, during the Gulf War the only comprehensive medical surveillance performed on deployed troops was done by the Navy on a group of about 40,000 Marines and sailors stationed in northeastern Saudi Arabia. This surveillance process routinely collected information on heat injuries,

diarrhea, skin conditions, respiratory conditions, injuries/musculoskeletal conditions, eye problems, unexplained fevers, psychiatric conditions, and other problems.³⁴² These reports were used to calculate weekly disease and non-battle injury rates and allowed medical personnel “to respond immediately to problems and apply appropriate countermeasures.”³⁴³ For example, detection through medical surveillance of high diarrhea rates in several units allowed medical personnel to avoid more cases by quickly identifying and removing certain local fresh foods which were found to be the cause. Other services did keep limited records on troop health, with Army records showing that approximately 200,000 soldiers were on sick call and 22,743 were hospitalized during the Gulf War deployment.³⁴⁴ However, this data cannot replace the kind of comprehensive ongoing medical surveillance performed by the Navy, which DOD has acknowledged “was a critical tool in immediately defining the major patterns of illness and injury in each Marine unit for most of the deployment.”³⁴⁵ Based on the effectiveness of this surveillance system to effectively respond to conditions affecting troop health as they occurred, it is likely that a similar theater-wide surveillance system could have provided a mechanism to track other health events during this deployment about which little reliable data now exists.

HEALTH ISSUES FOLLOWING DEPLOYMENT

VA AND DOD ESTABLISH REGISTRIES TO EVALUATE GULF WAR VETERANS' HEALTH COMPLAINTS

After returning from the Gulf War, veterans began to report numerous health complaints, including memory loss, muscle and joint pain, fatigue, skin rashes, and gastrointestinal problems. In response to this, VA, and later DOD, established registries to collect health-related information about these veterans. While registries can serve multiple purposes, these were established with the primary purpose of gathering standardized information from questionnaires to describe veterans' exposure and health histories and to conduct comprehensive physical and laboratory examinations. The registries also record identifying information so that individuals with certain illnesses or diseases could be followed over time to determine how their health status has changed, although neither VA nor DOD have used the registries for this purpose. Registry information that has been collected has been entered into a combined VA and DOD computerized database that was established under a July 1997 memorandum of understanding between the two departments.³⁴⁶ However, these registries cannot be used by themselves to determine how many Gulf War veterans are ill, because there is no way to know whether all ill Gulf War veterans have participated in these programs. These registries do provide useful information to describe the health status of the Gulf War veterans who have voluntarily chosen to participate. Indeed, this is currently the only data source to describe the health status of a large group of Gulf War veterans who have undergone a standardized examination process to document their health complaints. Nevertheless, as discussed below, there are shortcomings in the registry programs that should be addressed in order to maximize the usefulness of these registries in helping ill Gulf War veterans.

VA's Persian Gulf Registry and Uniform Case Assessment Protocol and DOD's Comprehensive Clinical Evaluation Program for Persian Gulf War Veterans

The VA Persian Gulf Registry was mandated in 1992 by Public Law 102-585 and modified in late 1995.³⁴⁷ Any Gulf War veteran may participate in the registry, even if that person has no current health complaints. The examination consists of two phases. During Phase I, the veteran completes a standardized questionnaire on exposures during the Gulf War and health complaints and undergoes a physical examination with laboratory testing.³⁴⁸ According to the VA registry protocol, veterans with health problems that are undiagnosed after a Phase I examination should be referred to more extensive Phase II evaluations. VA modified the original registry in 1995 in response to comments from veterans, the General Accounting Office, physicians, Congress, and others. The revised registry collects information on ten symptoms and diagnoses (the original registry format only allowed for recording three symptoms and diagnoses, even if the veteran had more than that number of health problems). It also collects more information on exposures and birth defects and specifically allows for recording whether the veteran has an undiagnosed illness. VA facilities are reportedly updating information obtained from veterans who participated in the first registry with the revised registry forms.

DOD established a Gulf War veteran health registry—the Comprehensive Clinical Evaluation Program for Persian Gulf War Veterans (CCEP)—in June, 1994. The CCEP is available for “DOD beneficiaries (Persian Gulf War veterans not on active duty or retired; members of the full-time National Guard who are Persian Gulf veterans; Persian Gulf War veterans who are members of the Ready Reserve/Individual Ready Reserve/Standby Reserve/Reserve who are placed on orders by their units; and eligible family members of such personnel) who are experiencing illnesses that may be related to their service in the Persian Gulf.”³⁴⁹ DOD's CCEP is similar, but not identical to VA's registry, and functions to collect information on Gulf War veteran exposures and current health complaints and to refer ill Gulf War veterans for further treatment.

Differences Between VA and DOD Gulf War Registries

Although the VA and DOD Gulf War registries have similar goals, they differ in important ways. The two registries use different questionnaires. For example, unlike the VA registry, the CCEP does not ask about undiagnosed illnesses. In addition, almost every person who participates in the CCEP receives a diagnosis, however, that diagnosis may be a sign, symptom, or ill-defined condition (such as headache or abdominal pain due to gas)³⁵⁰ Thus, while VA may state that a Gulf War veteran with a headache has an “undiagnosed illness,” DOD may state that person has been diagnosed with a headache. These points should be kept in mind when comparing the participants in the two registries, particularly because the frequency of diagnosed diseases and reported symptoms will vary because of these differences in collecting information.

External Reviews of the Registries

The DOD registry has been reviewed by nationally prominent scientists who served on IOM Committees and the PAC.³⁵¹ In 1994, the Department of Defense asked the Institute of Medicine to review the adequacy of the CCEP regarding “(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.”³⁵² The IOM made specific suggestions to improve the CCEP. It suggested that undiagnosed illness patients be treated as early in the disease process as possible based on their symptoms and that DOD should evaluate treatment and examination referral patterns of ill Gulf War veterans overall. It recommended that DOD improve its screening for depression and substance abuse and that it provide special training and debriefing for troops who are deployed. The IOM also suggested that DOD and VA coordinate their activities better, especially with regard to ongoing treatment of ill Gulf War veterans.³⁵³ The SIU believes that, to date, DOD and VA have not adequately addressed these IOM recommendations.

In September 1996, VA asked the IOM to review the VA registry with “specific emphasis on (1) the protocol, (2) its implementation and administration, (3) outreach efforts to inform veterans of available services, and (4) education of providers.”³⁵⁴ In a report issued in 1998 based on that review, the IOM provided a detailed and comprehensive set of recommendations for substantial changes to VA’s registry program. The IOM found that physicians did not always follow the written standard registry protocol. It also found that many primary care physicians ordered tests during the “Phase I” process that were technically part of the “Phase II” process of the written protocol, an approach that the IOM believed may be more clinically appropriate and indicated that the terms “Phase I” and “Phase II” should be dropped. The IOM developed a recommended pathway for diagnosing health problems of Gulf War veterans and encouraged its adoption in order to increase the role of primary care physicians, decrease spending of unnecessary resources, and establish a standard approach to patients with undiagnosed illnesses. The IOM also recommended that the initial registry evaluation be expanded. To accomplish this, it suggested that a national group of experts be brought together to determine how to revise the questionnaire, expand the laboratory examinations, and conduct periodic reevaluations of each portion of the initial examination. It also recommended that VA develop clinical practice guidelines for the most common “symptoms, and the difficult-to-diagnose, ill-defined, or medically unexplained conditions”³⁵⁵ of Gulf War veterans and for “the evaluation and management of women’s health issues,”³⁵⁶ and that VA should “plan for and include periodic reevaluations of the clinical needs of . . . undiagnosed patients.”³⁵⁷

The IOM further recommended that the VA develop a “formal mechanism that enables practitioners to provide feedback on the practice guidelines and the diagnostic process used in the VA clinical program for Persian Gulf Veterans.”³⁵⁸ In addition, the IOM suggested that the referral process be modified and that VA “establish an evaluation feedback mechanism that includes the elements of a performance improvement system.”³⁵⁹ It proposed better monitoring of quality of care

and patient satisfaction, more consistent data reporting across VA facilities, and systematic updating and incorporation into databases of individual patient information. The IOM also recommended improved outreach and education of primary health care providers.³⁶⁰ All of these recommendations would substantially improve VA's Persian Gulf Registry in its ability to provide quality care to Gulf War veterans, and the SIU believes that VA should implement these changes as rapidly as possible.

Demographic and Health Status Profiles of Registry Participants

Although both Gulf War veteran health registries have limitations and should be improved, the information they have collected to date does provide useful insight into the health complaints of a large group of those veterans. The most recent report describing registry participants provides information through December 1997 for the CCEP and November 1997 for the VA registry.³⁶¹ In all, 83,197 persons, or 12 percent, of the 696,530 potential Gulf War veterans, had participated in the registry programs. Table 2 sets out data describing demographic and other pertinent characteristics of those veterans.

The five figures that follow represent time lines of numbers of registry program participants on a monthly basis. As the figures demonstrate, participation in the VA registry gradually increased until the fall of 1994, then tapered off. A slight increase in participation followed the July 1996 announcement of the U.S. troop demolition of Khamisiyah with potential release of chemical agent into the atmosphere. Relatively large numbers of Gulf War veterans participated in the DOD CCEP from late 1994 through mid-1995. As was true for the VA registry, these numbers tapered off but then increased following the Khamisiyah announcement. Each month a larger number of male service members participated than female service members, but there was no other apparent difference in monthly participation on the basis of gender. Larger numbers of active duty personnel participated in the DOD CCEP than reservists, and reservists were more likely to participate in the VA registry than in DOD's. The VA registry has also had more equal participation of active duty and reservists as compared with the DOD CCEP. Larger numbers of Gulf War Army veterans participated each month than any other branch of the services, however, as shown by Table 2, the Army composed 50 percent of troops in the Gulf War deployment.

The registries also provide information about the most common diagnoses for participants. Unfortunately, the two sets of VA registry data (from the original registry and from the registry as revised in 1995) and the CCEP differ in how they have collected data, as described earlier, and thus are difficult to compare. However, Table 3 presents the most frequent diagnoses, and Table 4 presents the most common symptoms reported by participants. Although the registries differ, this information is still useful to develop a sense of the most common diagnosis and symptoms of the veterans who have participated. As can be seen from these tables, the diagnosis and symptoms of Gulf War veterans vary greatly and encompass multiple body systems. These diagnoses and symptoms should not be viewed as representative of all Gulf War veterans, but only reflecting the health problems of veterans who participated in the registries.

In testimony before the House Veterans' Affairs Committee, the VA Under Secretary for Health stated that from ten to twenty-five percent of registry participants have unexplained illnesses, depending on how that term is defined, and that he believes this is about the same percentage that would be expected in a general medical practice outside of VA.³⁶² Another VA official testified at that hearing that about twelve to fifteen percent of participants have no health problems but have voluntarily chosen to take part in the registry.³⁶³ These statements, however, should be reevaluated based on the limitations of the registry that were pointed out by the IOM.

Table 2. Characteristics of United States Military Service members Who Participated in the Gulf War (GW) Theater of Operations and the Department of Defense (DOD) or Department of Veterans' Affairs' (VA) Gulf War Registries, 1997.

Characteristic	Gulf War Service members (n= 696,530)	DOD and VA Gulf War Registry Participants (n= 83,197) %
Male gender	89	90
Race		
White	65	62
Black	22	26
Hispanic	5	6
Other/Unknown	8	6
Age group (1991)		
< 25	42	33
25-34	40	39
35-44	16	22
45-54	3	5
55-64	< 1	< 1
≥ 65	0	0
Service branch		
Army	50	77
Marine	15	11
Navy	23	6
Air Force	12	7
Unit Status		
Active	84	71
Reserve/Guard	16	29
Rank		
Enlisted	89	92
Officer	10	6
Other/Unknown	1	2

Note: Percentages may not total to 100 due to rounding.

Figure 6. Monthly Numbers of Participants in a Gulf War Exam by Registry Type, August 1992 through November 1997.

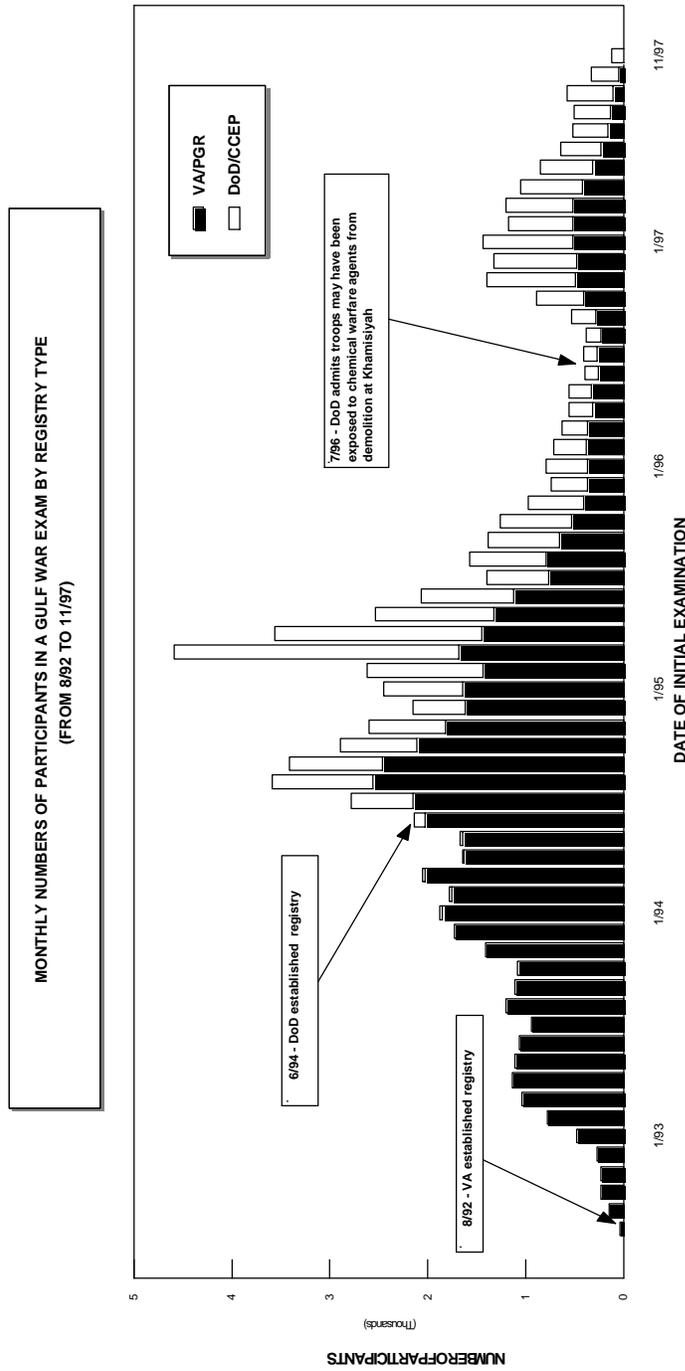


Figure 7. Monthly Numbers of Participants in a Gulf War Exam by Gender, August 1992 through November 1997.

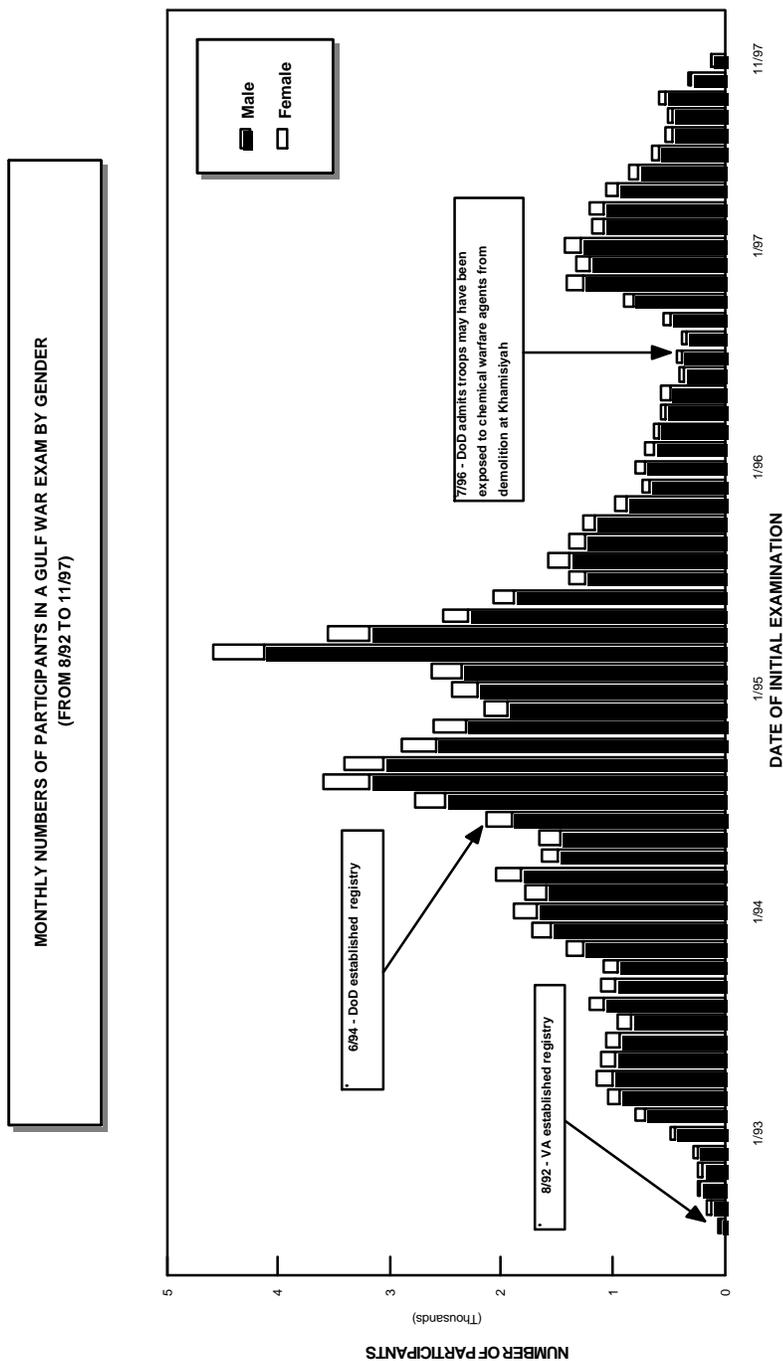


Figure 8. Monthly Numbers of Participants in a Gulf War Exam by Registry Type and Unit Component During the Gulf War, August 1992 through November 1997.

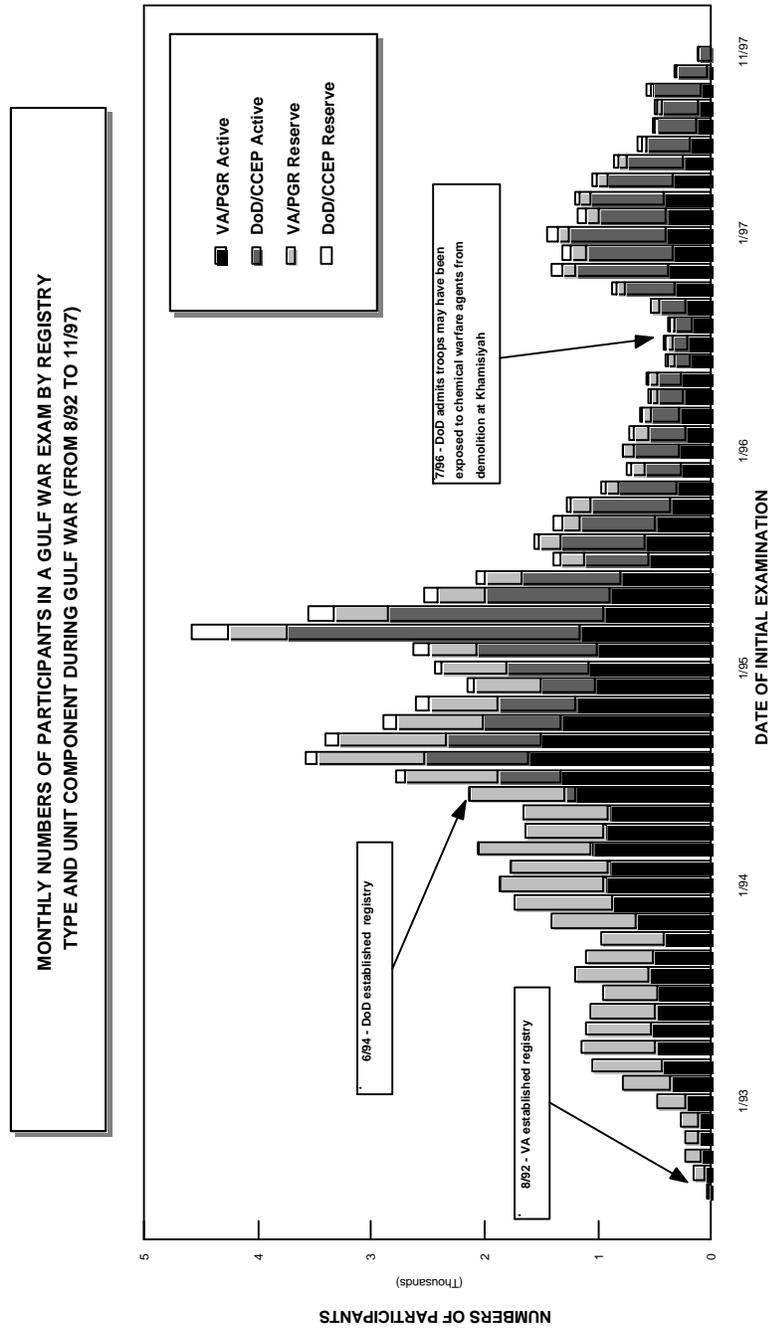


Figure 9. Monthly Numbers of Participants in the Department of Veterans' Affairs Persian Gulf Registry Program (VA/PGR) by Branch of Service, August 1992 through October 1997.

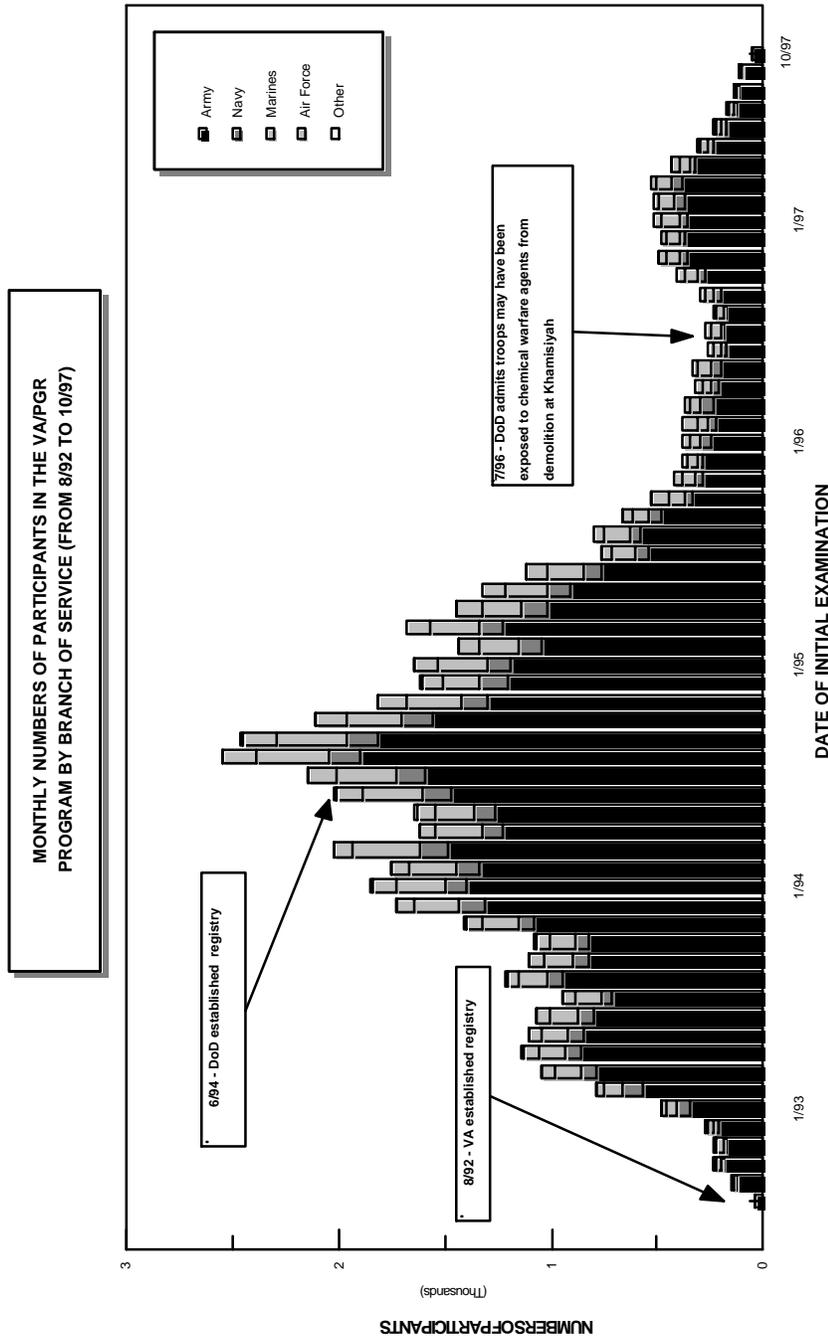


Figure 10. Monthly Numbers of Participants in the Department of Defense's Comprehensive Clinical Evaluation Program (DOD/CCEP) by Branch of Service, January 1994 through November 1997.

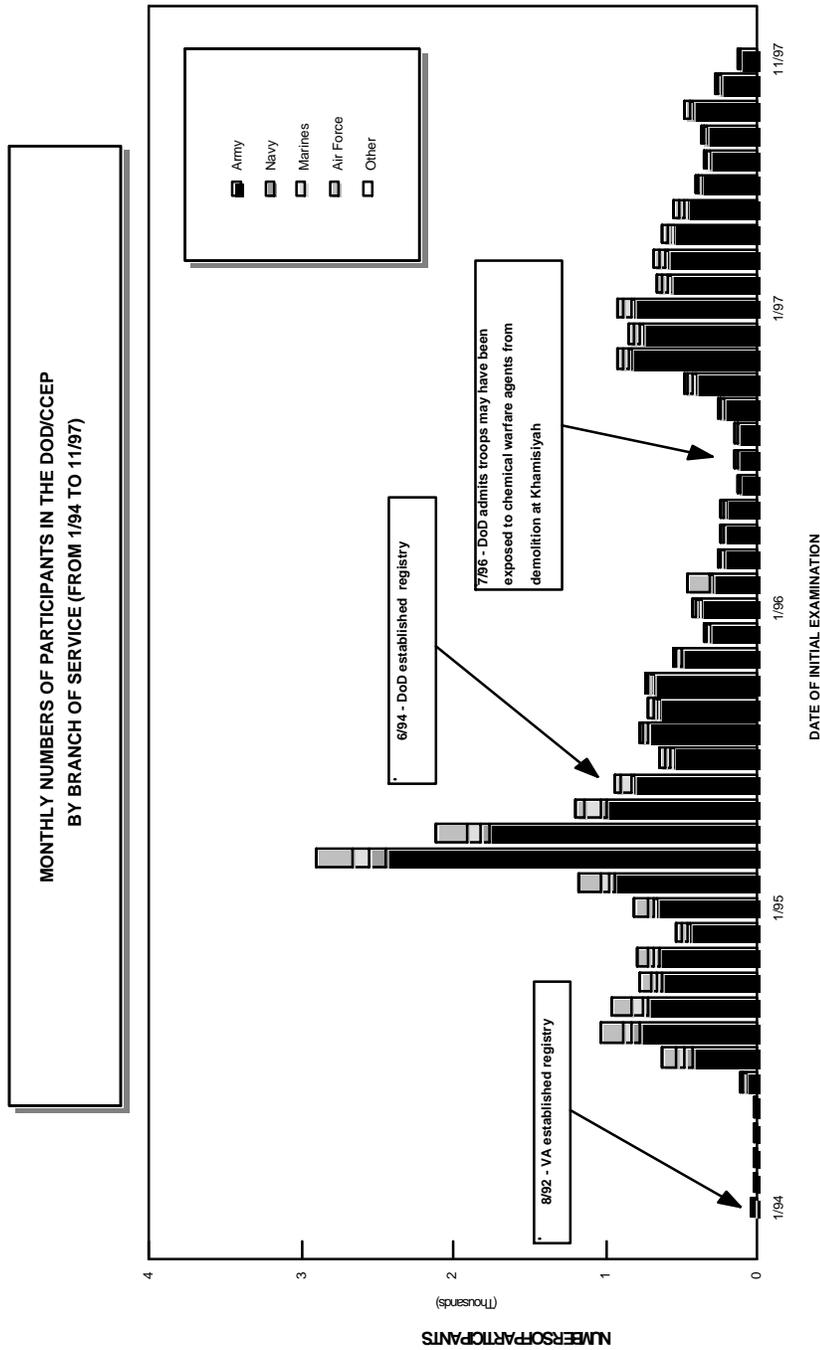


Table 3. Distribution of Diagnoses of United States Military Personnel Who Participated in the Gulf War (GW) Theater of Operations and the Department of Veterans' Affairs (VA) Gulf War Registry (PGR) or the Department of Defense's Comprehensive Clinical Evaluation Program (CCEP), 1998.³⁶⁴

Diagnosis	Old GWR (n= 48,251) %	New GWR (n= 9,002) %	CCEP (n= 27,747) %
Musculoskeletal and Connective Tissue	25	36	48
Mental Disorders	15	33	35
None Given	32	26	21
Skin and Subcutaneous Tissue	13	19	19
Respiratory System	14	18	16
Nervous System	8	16	17
Digestive System	11	16	20
Injury and Poisoning	5	11	3
Circulatory System	7	10	8
Infectious Disease	7	9	9
Genitourinary System	3	6	5
Neoplasm (Malignant)	< 1	1	< 1

Table 4. Distribution of Common Complaints of United States Military Personnel in the Gulf War (GW) Theater of Operations Who Participated in the Department of Veterans Affairs (VA) Gulf War Registry (PGR) and the Department of Defense’s Comprehensive Clinical Evaluation Program (CCEP), 1998.³⁶⁵

Complaints	Old PGR (n= 48,251) %	New PGR (n= 9,002) %	CCEP (n= 27,747) %
Muscle, Joint Pain	16	51	58
Fatigue	21	25	52
Headache	18	27	45
Loss of Memory/Other General Symptoms	14	30	40
Shortness of Breath	8	11	40
Diarrhea/Other	5	14	27
Gastrointestinal			
Skin Rash	19	26	25
Sleep Disturbances	6	13	18
No Complaint	12	10	7

GULF WAR VETERANS AND THE DILEMMA OF UNEXPLAINED ILLNESSES

Data from the VA and DOD registries demonstrate that many Gulf War veterans are ill with health complaints that involve a variety of body organ systems (e.g., musculoskeletal, gastrointestinal, and nervous systems). As the registry data indicates, Gulf War veterans do not share a single medical diagnosis or “disease” characterized by a single set of symptoms (complaints) and signs (objective evidence of disease, such as temperature or abnormal laboratory results).³⁶⁶ Thus, there is no single “Gulf War syndrome.” Rather, these veterans are best described as suffering from unexplained “illnesses,” some of which very debilitating but are nevertheless not easily identified by medical professionals as part of a known clinical syndrome.

This distinction between “diseases” and “illnesses” is not unique to Gulf War veterans but is one that hinders any research investigation of new, unexplained, or previously unrecognized conditions

or diseases.³⁶⁷ One way to understand this distinction is to view “illness” as the health changes experienced and reported by the patient while “physicians diagnose and treat ‘diseases’ . . . abnormalities in the structure and function of body organs and systems.”³⁶⁸ Thus, Gulf War veterans who were physically and mentally healthy enough to be deployed but after the war developed symptoms and decreases in physical functioning after the war have experienced “illness.” However, as many Gulf War veterans have reported, their initial complaints that they were ill as a result of their Gulf War service were countered by physicians’ responses that they could find nothing wrong and that there was no “disease.”³⁶⁹ As a result, many Gulf War veterans are frustrated and left with many unanswered questions about why they are ill and whether their health will improve. Similarly, health care providers also report frustration in being unable to provide treatment that effectively improves the health of Gulf War veterans with unexplained illnesses.

Understanding the Link Between War Experiences and Health

The unexplained illnesses of Gulf War veterans do not represent the first time that concerns about veterans’ health have arisen after a war. Unexplained or poorly understood illnesses among veterans were identified during the Civil War and both World Wars. Post-traumatic stress disorder among Vietnam veterans was first referred to as “post-Vietnam syndrome.”³⁷⁰ However, historical medical data—especially clinical descriptions dating back to the 1800s and early part of this century—are difficult to compare with modern medical data, especially because “the psychological aspects of illnesses were not as well appreciated and reported in the past.”³⁷¹ Moreover, modern improvements in overall health and nutrition make it difficult to compare the health of military populations of different eras.³⁷²

However, unanswered questions about Gulf War veterans’ health can be better understood by reviewing past attempts to examine the relationship between veteran health and exposure to combat and war trauma. One of the few studies that examined chronic long-term health problems associated with war trauma and post-traumatic stress disorder (PTSD) in Vietnam veterans found that those with a history of PTSD were at higher risk for a number of physical diseases than those without PTSD. The study found those with PTSD to have a higher lifetime prevalence of a range of physical diseases as many as 20 years after military service.³⁷³ This study suggests there may be a strong link between exposure to trauma and a broad spectrum of physical diseases, such that the medical implications of exposures to severe environmental stress like combat should be considered when examining illnesses among combat veterans.³⁷⁴ Moreover, the literature on physical health outcomes associated with exposure to a variety of traumatic events has been described as “impressive for the consistency of results showing that exposure to catastrophic stress is associated with adverse health reports, medical utilization, morbidity, and mortality among survivors.”³⁷⁵ This strong evidence of a link between the fact of wartime service and subsequent health problems should be drawn upon by VA and DOD in devising prevention and medical follow-up strategies for future military deployments.

ATTEMPTS TO DEVISE CASE DEFINITIONS FOR UNEXPLAINED ILLNESSES

Another problem presented by the “unexplained illnesses” of Gulf War veterans is that without an identifiable disease or diseases, research into possible causes of these illnesses is made much more difficult. In order to do epidemiological studies on Gulf War veterans—that is, conducting research on the illnesses affecting members of that group of veterans and what factors may have triggered them—researchers must first determine what constitutes an illness by developing a case definition. “Case definitions” describe what specific criteria must be met in order to classify a person as having a particular disease and ensures that those being studied have as “homogeneous a disease entity as possible”³⁷⁶ so that studies include only those with the same disease when searching for a possible cause for that disease. Although there have been attempts to develop a case definition for Gulf War veterans with undiagnosed illnesses, there is no accepted definition. Research funded by CDC is now underway to develop an accepted case definition for Gulf War undiagnosed illnesses.³⁷⁷ The purpose of the study, to be conducted by the Robert Wood Johnson Medical School, is to “characterize and compare alternative classifications for symptoms and functional disability which remain medically unexplained in Gulf War veterans.”³⁷⁸ Advantages to developing a case definition for undiagnosed illnesses in Gulf War veterans include aiding researchers in identifying groups at increased risk of illness and providing clues about possible causes of or what risk factors may be associated with the illness.

Diagnosable Conditions and Death Rates in Gulf War Veterans

In addition to undiagnosed illnesses, as the entries on Table 3 indicate, many Gulf War veterans have diagnosable health conditions. Researchers have examined the morbidity (meaning “prevalence or incidence of a disease or of all diseases in a population”³⁷⁹), mortality (rates of death), and reproductive outcomes for Gulf War veterans to detect any patterns or increases in specific diagnoses or deaths in this population. These studies have been summarized previously by the PAC and IOM³⁸⁰ and are addressed in several of the consultant reports in Chapter Four and the Appendix. In general, studies to date have not found Gulf War veterans to have an increased number of deaths, hospitalizations for disease, or birth defect rates among their offspring as compared with non-deployed veterans.³⁸¹ These findings must be viewed in light of limitations of these studies such as inability to accurately estimate exposures or to generalize results to the entire Gulf War veteran population because, for example, some groups at increased risk of health problems were excluded.

However, an increase in accidental death, particularly from motor vehicle accidents has been found among Gulf War veterans. This heightened death rate from accidents has been observed for Vietnam and Korean War veterans as well.³⁸² For example, a CDC study found a significantly higher postwar death rate from motor vehicle accidents among Army veterans who had served in the Vietnam War compared to Vietnam-era Army veterans who were stationed elsewhere. This increase did not appear to be related to elevated blood alcohol levels.³⁸³ Moreover, a study of Vietnam-era

female veterans found that women veterans who had served in Vietnam had a threefold risk of dying from injuries sustained in a motor vehicle accident than women veterans who did not serve there.³⁸⁴

CONCERNS ABOUT THE HEALTH OF GULF WAR VETERANS' FAMILY MEMBERS

As VA and DOD developed registry programs to address Gulf War veterans' health concerns, reports surfaced of developing health concerns in the family members of Gulf War veterans, including fears about a higher incidence of birth defects in children of Gulf War veterans. There were anecdotal reports of spouses and children of veterans developing similar symptoms, and concerns about the reproductive health of the spouses and partners of Gulf War veterans. In addition, some feared that the health problems experienced by Gulf War veterans may have been secondary to an infectious agent or transmittable illness, despite the lack to date of clinical findings or scientific evidence to support such a theory.

Persian Gulf Spouse and Children Examination Program

To address these concerns about family member health, the Persian Gulf Spouse and Children Examination Program was created by Congress under Section 107 of the Persian Gulf War Veterans' Benefits Act (P.L. 103-446). This legislation provided for VA to conduct a pilot study to contract with medical center affiliates to perform medical exams of spouses and dependents of Gulf War veterans. Congress authorized \$2 million for this pilot program and directed VA to enter information collected under the program into the Persian Gulf Registry for the purpose of evaluating for any potential association between health problems of the family members of veterans and the veterans' service in the Gulf.

There was significant resistance by VA to implementing this program, and debate over the intent of the legislation authorizing the spouses and dependents program continued for well over a year after the law was enacted. VA had been directed to start this program immediately after enactment in November 1994, but the program did not begin until 18 months later.³⁸⁵ VA sought to interpret the legislative intent in creating the program as providing for an already-planned epidemiological study of randomly selected spouses and children of Gulf War veterans. However, Congress and the White House both saw the statute as clearly providing a program for voluntary medical evaluations (but not treatment) of spouses and children with health concerns potentially related to the veterans' Gulf War service.³⁸⁶ The Persian Gulf Spouse and Children Examination Program was finally started by VHA on April 1, 1996, with 36 VA medical centers across the country designated to coordinate the program.

In reviewing VHA's implementation of this program, GAO found a number of significant problems. Some of these problems appear related to VHA's increasing decentralization of health care programs, with little oversight existing except at the level of the 22 Veteran Integrated Service Networks (VISNs). Because VA medical centers do not provide care for spouses or children of

veterans, they were to contract with an affiliate medical center to provide program examinations. However, a number of the designated medical centers failed to do so, with the result that evaluations for spouses and children of Gulf War veterans were in fact not being provided and VHA headquarters officials were largely unaware of this fact until GAO made inquiries about the program in January of 1998.³⁸⁷ Turnover in key VA medical center personnel and VA's failure to require monthly activity reports from coordinating centers until a year and a half after the start of the program were identified by GAO as reasons why VA had not fully monitored this program's status.

GAO also found uneven efforts to inform Gulf War veterans of the availability of the program and a number of potential barriers to participation in the Persian Gulf Spouse and Children Examination Program. For example, veterans' requests for examinations cannot be made through a local medical center; they must be coordinated through the Persian Gulf War Veterans' Helpline, with the average time from an initial request to the completion of the examination stretching to over 15 weeks. Geographic distance from a center providing exams was another major deterrent for many families, especially because VA does not reimburse for travel expenses. As of January 1998, 2,802 evaluations had been requested but only 872—less than one-third—had been completed. GAO reported that less than seven percent of the \$2 million appropriated for this program—only \$148,916—had been spent as of February 1998.³⁸⁸

In order to improve participation rates, GAO recommended that VA simplify the process for requesting and scheduling evaluations, offer the examinations in more locations, seek approval to reimburse participants for travel expenses, and increase the capacity of VA's Office of Public Health and Environmental Hazards to monitor the implementation of the program in the field. GAO noted that the program of clinical examinations offered through this program are not likely to resolve the issues related to whether illnesses among family members are related to the illnesses of Gulf War veterans.³⁸⁹ However, because the Persian Gulf Spouse and Children Examination program provides family members of veterans with an opportunity to visit a physician and receive a free medical examination, the greater value of the program may be that it is a way to address and perhaps resolve the fears and concerns of individual veterans as to whether exposures that they may have experienced during their service may have adversely affected the health of their families.

OVERVIEW OF INDEPENDENT SCIENTIFIC PANEL REPORTS ON GULF WAR HEALTH CONSEQUENCES

As part of the national response to concerns about the emergence of unexplained illnesses and health problems of Gulf War veterans, a number of independent, scientific panels were convened to examine these health issues and to make health policy recommendations to the federal agencies involved. This section provides a brief, chronological overview of the health findings of the major independent scientific review boards that examined these issues. Published reports are available on the complete findings and recommendations of each of these groups. The common goals of all these groups were to study reports of undiagnosed and diagnosed illnesses among Gulf War veterans, to

examine the environmental exposures that were present in the Gulf, to evaluate the biological plausibility of various illness etiologies, and to review the information available on the incidence and prevalence of these health problems.

Institute of Medicine: Health Consequences of Service During the Gulf War

In response to Public Law 102-585, the Committee to Review the Health Consequences of Service During the Persian Gulf War was assembled in December 1993 by the Medical Follow-Up Agency of the Institute of Medicine (IOM). The IOM issued an initial report in January 1995 and a final report in October 1996. It was tasked to assess the effectiveness of DOD and VA to collect and maintain data on the health of Gulf War veterans and make recommendations on improving the collection and maintenance of such data. It was also asked to determine whether there was a sound scientific basis for an epidemiological study of the health consequences of service in the Gulf, and if so, to make recommendations about the design of such studies. The complete set of findings and recommendations are contained in the Institute of Medicine's 1995 and 1996 reports, Health Consequences of Service during the Persian Gulf War.

The IOM committee found that problems with the collection and maintenance of health information of service-related personnel had adversely affected any subsequent efforts of researchers and medical caregivers to evaluate Gulf War veterans' health concerns. They identified the need for DOD and VA to work together to "develop, fund, and staff medical information systems that include a single, uniform, continuous, and retrievable medical record" for each service member.³⁹⁰ The IOM committee also recommended that VA and DOD work together to expand and expedite plans for a shared basic epidemiological data system, the Defense Medical Epidemiological Database.³⁹¹ Their report stressed the need to examine DOD capabilities to evaluate the health significance of geographically defined exposures of troops over time in areas of conflict, and they recommended that DOD support military medical preparedness through increased monitoring of natural and man-made environmental exposures and planning for rapid response and investigation of known or possible exposures in specific theaters of operation. The importance of accurate data collection and maintenance of such exposures was also emphasized.³⁹²

The final report of the IOM committee noted that a number of large epidemiological studies were already well underway and thus no new nationwide study of Gulf War veterans was advised. The committee recommended that death rates of Gulf War veterans should be monitored on a regular basis for up to 30 years and compared to rates for Gulf War-era veterans who were not deployed to the Gulf.³⁹³ Finally, the IOM committee recommended that the Congress, VA, and DOD should require that unless there are clear and justifiable reasons not to do so, requests for research proposals on Gulf War-related health issues should be publicly announced to the scientific community at large and peer reviewed by appropriately qualified scientific experts who would evaluate the scientific merit and rigor of such proposals and then make funding recommendations to the granting agencies.³⁹⁴

National Institutes of Health (NIH) Technology Assessment Workshop

The NIH Technology Assessment Workshop on the Persian Gulf Experience and Health convened on April 27-29, 1994 and was sponsored jointly by HHS, VA, DOD, EPA, and the Office of Medical Applications of Research of NIH. The panel was composed of scientific experts in fields including environmental and occupational health, international medicine, neurology, and toxicology, all of whom were drawn from outside the federal government. The panel noted problems with the lack of clear information about the types and levels of possible exposures in the Gulf and the need for a case definition. The panel suggested that there may be multiple illnesses with overlapping symptoms and causes and criticized the failure to develop a uniform protocol to examine Gulf War veterans across military service branches, VA facilities, and civilian physicians. Further, it suggested that the failure to do so contributed to the lack of a clear description of Gulf War veterans' health problems. The panel also recommended types of epidemiological studies that could help address these issues.³⁹⁵

Defense Science Board Task Force on Persian Gulf War Health Effects

The Defense Science Board Task Force on Persian Gulf War Health Effects was also established in 1994 by the Under Secretary of Defense for Acquisition and Technology.³⁹⁶ This Task Force was set up to review available intelligence information and reports regarding possible exposures to chemical and biological weapons, scientific and medical literature on health effects of low level exposures to nerve agents, and other potential health consequences resulting from potentially hazardous exposures in the Gulf. In its report, the Task Force concluded that there was “no persuasive evidence that any of the proposed etiologies caused chronic illness on a significant scale in the absence of acute injury at initial exposure.”³⁹⁷ It described the overall health experience of this conflict as very favorable in comparison to other wars and suggested that the background of low non-combat and combat-related disease during the Gulf War had highlighted “residual health problems” in this population.³⁹⁸

The Task Force also concluded that there was no scientific evidence that chemical or biological weapons were used during the Gulf War nor was there evidence of exposures to BW or CW agents, with the exception of a single instance of mustard agent blister injury in the postwar period. It found no epidemiological evidence to support the existence of a single, well-defined syndrome, suggested that a number of cases resembled a chronic fatigue syndrome, and recommended that clinical treatment be directed toward symptom management. The panel recommended significant improvements in DOD's pre- and post-deployment medical evaluations and record keeping. Finally, the Task Force recommended that as “high-tech, low-casualty military campaigns in exotic places” continue, further research is needed to evaluate residual health effects of such deployments.³⁹⁹ However, following the 1996 disclosure of a low-level release of nerve agent during the U.S. demolition of the Khamisiyah munitions depot, the Task Force's chair, Dr. Joshua Lederberg, questioned some of the report's findings. He stated in an interview that the panel was unaware of the events at Khamisiyah when it wrote its report and suggested additional research into the potential for chronic health effects as a consequence of low-level exposures to nerve agents.⁴⁰⁰

The Presidential Advisory Committee on Gulf War Veterans' Illnesses

On May 26, 1995, President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC). The PAC was tasked with conducting a full review of governmental activities related to Gulf War veterans' illnesses, including research, coordinating efforts, medical treatment, outreach, risk factors, and chemical and biological weapons. In addition, it was asked to examine the work of other governmental and nongovernmental scientific panels. The 12-member panel, made up of veterans, policy experts, scientists, and health care professionals, held a series of open meetings from August 1995 through November 1996. Following release of its final report in December of 1996, the President renewed the PAC's charter to continue oversight of DOD investigations of possible chemical and biological warfare exposures during the Gulf War. The PAC issued a supplemental special report in October of 1997.

In its final report, the PAC noted important parallels in the post-conflict health experience of Gulf War veterans' and those of Vietnam veterans, with several recommendations focused on the need to better understand, and hopefully prevent, veterans' post-conflict health concerns.⁴⁰¹ They recommended that a Presidential Review Directive be issued to develop "an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions."⁴⁰² The 1997 supplemental report noted continued difficulties with DOD's medical record keeping, assessment of environmental health threats, and other health measures such as compliance with FDA agreements on the use of an investigational vaccine in the Bosnia deployment. In particular, it characterized DOD's performance in complying with the FDA agreement for the investigational new drug, a vaccine for tick-borne encephalitis, as an "abysmal failure" and concluded that DOD had shown itself incapable of evaluating such investigational products during deployments.⁴⁰³

The PAC concluded that in general the government had acted in good faith in responding to the health concerns of Gulf War veterans but found shortcomings in the availability of treatment for Gulf War veterans, especially in the areas of mental health and reproductive health. They described concerns about VA's lack of coordinated follow-up care of Gulf War veterans by knowledgeable health care providers. The PAC also found that additional research was needed in areas such as the long-term health effects of low-level exposures to chemical warfare agents and possible synergistic relationships between PB and other exposures in the Gulf, but cautioned that federal research funds should not be awarded outside a competitive peer review process to keep research funding a scientific process rather than a political one.⁴⁰⁴ The PAC also expanded upon previous evaluations of the potential effects of stressful wartime exposures on the subsequent health of veterans, noting the many physical manifestations of stress, including that it can "affect the brain, immune system, cardiovascular system, and various hormonal responses."⁴⁰⁵ A number of the PAC's comments on stress were imprecisely phrased and, taken out of context, were criticized for focusing on "stress" to the exclusion of other possible risk factors that may be causes of Gulf War veterans' unexplained illnesses.

LONG-TERM HEALTH CONSEQUENCES OF GULF WAR EXPOSURES

Because of the lack of exposure and health data from the Gulf War and the inherent complexity of the inquiry into why Gulf War veterans are ill, a complete answer may never be possible. However, the SIU engaged several nationally recognized scientific experts to provide some specialized insight into the difficult questions of potential short- and long-term health effects from a variety of exposures Gulf War veterans likely experienced. The SIU identified experts with the assistance of independent organizations, such as the American Association for the Advancement of Science, U.S. Centers for Disease Control and Prevention, National Institutes of Health, and Association of Occupational and Environmental Clinics. These experts looked at various types of exposures in their area of specialization and the potential health effects associated with those exposures. Experts included researchers who have examined short- and long-term health effects associated with pesticide use in populations who work with pesticides to provide observations on the use of pesticides in the Gulf and any expected adverse health effects. Others specialized in health effects of indoor and outdoor air pollution in the general population, and assessed air pollutants in the Gulf and their potential health effects. Still other experts reviewed available information about exposures to the wide range of chemicals present in the Gulf (e.g., solvents, depleted uranium, pyridostigmine bromide, organophosphates, etc.) to provide information about the potential risks for the development of central nervous system damage, reproductive problems, and cancers.

In reports submitted to the SIU, these experts provided information on what health effects could be expected in the general population, the veteran population who had been in the Gulf, or subgroups of that population who may be at increased risk. The consultants also reviewed existing scientific studies on Gulf War veterans, as well as other populations who have experienced similar exposures (e.g., individuals who work with those particular chemicals). In their reports, most of the consultants noted that the limited information to document exposures during the Gulf War hindered their capability to adequately address what types of health problems, if any, could occur from those exposures. The consultants also provided recommendations on additional studies that could be done, and what health practices the military should consider changing or implementing. Summaries or the full text of their work appear in the following chapter; the full text of the summarized reports appears in the Appendix. Because these reports necessarily are based on information now available, the SIU does not regard these expert reports as the final word on these subjects. However, the SIU believes that the work of these experts provides a broad picture of what is known about possible reasons for illnesses among Gulf War veterans and contains important recommendations for the future. These consultant reports should prove valuable in the ongoing national dialogue about why so many Gulf War veterans are ill.

CURRENT STATE OF TREATMENT OF GULF WAR VETERANS BY DOD AND VA

Department of Defense: Walter Reed Army Medical Center's Gulf War Health Center

To help coordinate implementation of its CCEP registry programs for Gulf War veterans and to provide primary and tertiary care CCEP evaluations, in 1994 DOD created a Gulf War Health Center at Walter Reed Army Medical Center.⁴⁰⁶ DOD then determined that a multidisciplinary treatment program also was needed for care of Gulf War veterans with persistent and unexplained physical symptoms and in March of 1995 also began a Specialized Care Program at Walter Reed.⁴⁰⁷ At DOD's request a panel of national experts reviewed the program and its recommendations were implemented in the program's design. To date, this is the only treatment program in DOD or VA providing a "multidisciplinary chronic pain treatment approach for those with persistent Gulf War related physical symptoms,"⁴⁰⁸ an approach which studies have shown is highly effective in treating and reducing pain and in improving both physical and emotional functions in individuals suffering chronic pain.⁴⁰⁹

The program provides intensive multidisciplinary outpatient treatment over a three week period for Gulf War veterans with chronic, unexplained symptoms. The program's goal is to reduce the severity and frequency of these veterans' physical symptoms and to improve their quality of life, physical functions, and ability to work.⁴¹⁰ Initial research indicates that Gulf War veterans who have enrolled in Walter Reed's Specialized Care Program had been utilizing health care services at a higher rate, yet they had continued to report large numbers of physical symptoms that seriously impaired their ability to function. Preliminary followup data from the SCP suggests that Gulf War veterans who have participated in the program have reported notable improvement in their physical and social functioning.⁴¹¹ As of February 1998, 130 active military personnel and veterans who served in the Gulf have been through this clinical program. Although the program typically takes only 8 to 10 Gulf War veterans at a time, the fact that only 130 veterans have been through it during a three year period reflects an unfortunately low use of this innovative and apparently effective health care program for Gulf War veterans.

This low rate of use may be the result of a number of potential barriers that this investigation has identified. First, some active duty personnel who are ill report that it is difficult to get unit commanders to agree to give them leave for the three weeks that is necessary to participate in the program.⁴¹² Reservists who are interested in the program have expressed concerns that they will lose wages for the time away from their job unless it is possible to officially activate them for reserve duty for the time spent in treatment.⁴¹³ Also, some servicemembers have expressed concerns about requesting a referral to the program because they are worried that admission of health problems related to their Gulf War service will adversely affect their promotion potential or their possible retention in a downsizing military because there continues to be a stigma associated with Gulf War illness or health problems in the military.⁴¹⁴ It is unclear how much outreach is being done to military servicemembers who served in the Gulf or to their military physicians to notify them that the program

exists. Finally, while this program would be equally beneficial in meeting VA's Gulf War veteran health care programs and goals, there has been little communication between VA and DOD to explore the program's potential as a joint VA and DOD clinical program. Resolving these problems would go far in making the unique aspects of this important program more widely available to many Gulf War veterans who could benefit from its approach.

VHA Treatment of Gulf War Veterans

Since the end of the Gulf War in 1991, many veterans have been treated at VA facilities. VHA testimony before Congress in February 1998 stated that 220,000 Gulf War veterans have made 2.5 million ambulatory health care visits to a VA health care facility, 80,000 have been counseled at veterans' centers, and 22,000 Gulf War veterans have been hospitalized for both service-connected and non-service connected reasons.⁴¹⁵ In addition to providing treatment through the existing VA health care programs, recent legislation⁴¹⁶ directs VA to establish ten demonstration projects by July 1, 1998, in order to test new treatment approaches, including multidisciplinary treatment to manage symptoms and to improve satisfaction with treatment of Gulf War veterans with undiagnosed illnesses. These treatment centers have the potential to provide important advances in determining how best to care for Gulf War veterans with undiagnosed illnesses.

SIU Survey of VA Hospitals on the Status of Gulf War Health Programs

As part of this investigation, SIU investigators conducted a telephone survey of 23 VA hospitals across the country to learn more about programs and treatment being provided to Gulf War veterans. The survey's goal was to assess what an average caller's experience would be when phoning a VA medical center to get basic information about Gulf War veteran health programs at that facility. SIU investigators reached individuals who could answer basic questions about Gulf War veterans' programs at 17, or three-fourths, of the 23 medical centers. In the other six cases, three times SIU investigators were connected to the wrong department and then told that someone would call back with the name of the correct VA employee. However, in none of those cases did anyone from that medical center return the call. In one instance, no one answered the medical center's main number despite repeated tries and long waits. In attempting to contact the other two medical centers, a recording stated that the number had been disconnected but provided no new number at one facility, and at the other the main number was busy each time when called despite seven separate tries over a four day period.

Of the 17 hospitals where information on Gulf War programs was available, seven (41 percent) knew that their facility could determine how many Gulf War veterans were being currently followed for treatment. At one hospital, registry examinations were given by a nurse practitioner rather than a physician. All 17 of the facilities surveyed reported that primary care physicians who treated Gulf War veterans had received some training about the problems of Gulf War veterans, including conference attendance as well as written materials. At two facilities, individuals reported that their

facility did no outreach or marketing to Gulf War veterans, and a third of the individuals contacted did not know if their hospital did so. Attempts were also made to interview physicians who were responsible for the Persian Gulf War Registries to learn their general impressions about the health care needs of Gulf War veterans. Six physicians were eventually contacted, and all also treated Gulf War veterans. They suggested ways to improve treatment that included ensuring that adequate amounts of time are provided for physicians to counsel as well as examine veterans and improving the information VA provides to Gulf War veterans. Although this limited survey involved only a small sample of all VA facilities, at a minimum the results suggest that barriers exist to obtaining good and timely information on VHA's programs for Gulf War veterans.

CURRENT STATE OF FEDERAL RESEARCH PROGRAMS ON GULF WAR HEALTH ISSUES

Persian Gulf Veterans Coordinating Board Research Working Group

On August 31, 1993, President Clinton designated VA as the lead agency for the coordination of the federal research program on Persian Gulf veterans' illnesses, and the Persian Gulf Veterans Coordinating Board was formed. The Board's Research Working Group (RWG) includes representatives of VA, DOD, HHS, and EPA. This group is charged with ongoing evaluation of the direction of federal research in this area. Tasks of the Research Working Group include: identifying testable research hypotheses; making recommendations for research in identified high priority areas; coordinating research among the agencies involved; reviewing developing research concepts; collection and dissemination of peer-reviewed scientific research; and "ensuring that all research collected under the umbrella of the RWG undergoes appropriate scientific peer-review, and that the results of peer-review lead to appropriate actions by the sponsoring agencies."⁴¹⁷

Federal Research Funding Levels and Priorities

Federal agencies had spent a total of \$77.4 million on research on Gulf War veterans' illness-related issues from fiscal year (FY) 1994 through FY 1997. Of that total, DOD spent approximately \$62.5 million, VA spent \$10.8 million, and HHS spent \$4.1 million.⁴¹⁸ During FY 1998, the RWG projects that an additional \$37.9 million will be spent on Gulf War research.⁴¹⁹

A summary and breakdown of research categories and levels through 1997 is provided in Figures 11-13.⁴²⁰

Figure 11. Persian Gulf Illness Research Type

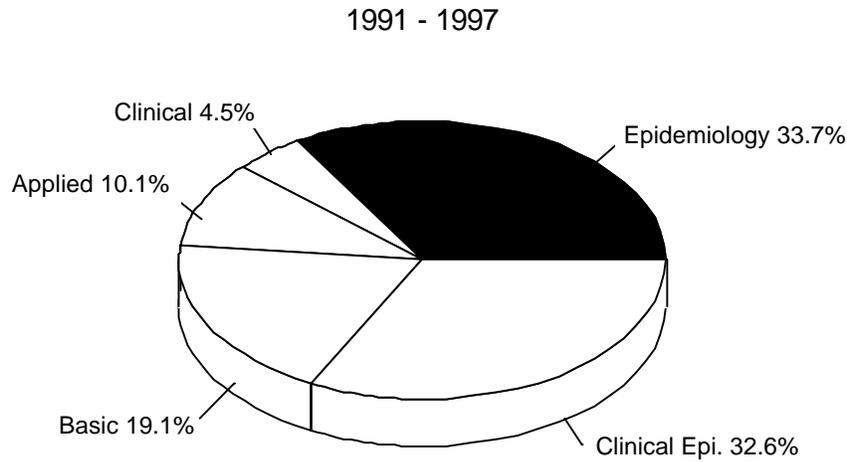
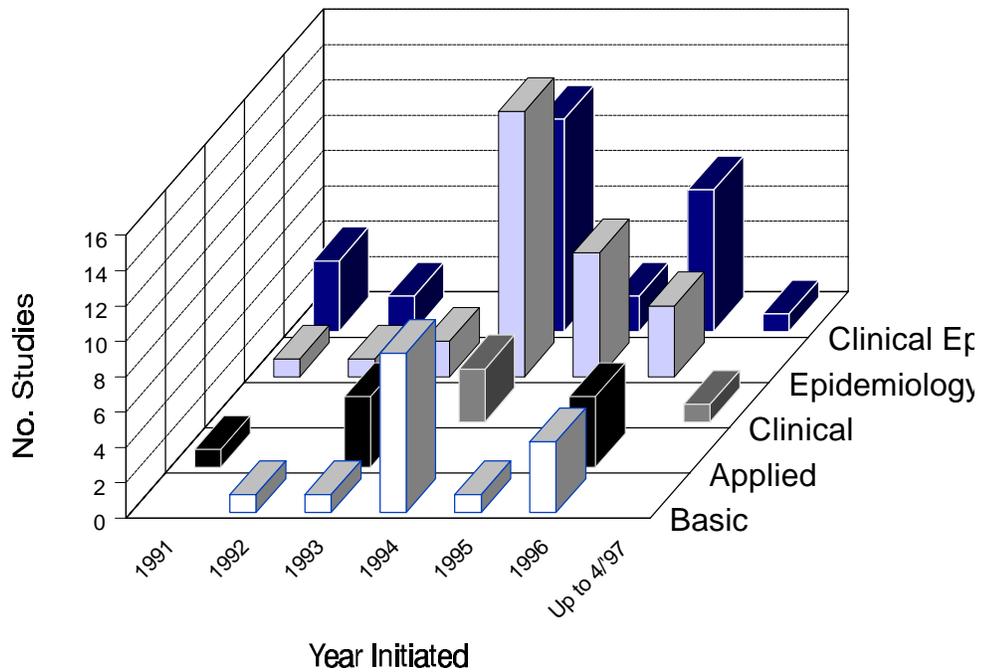
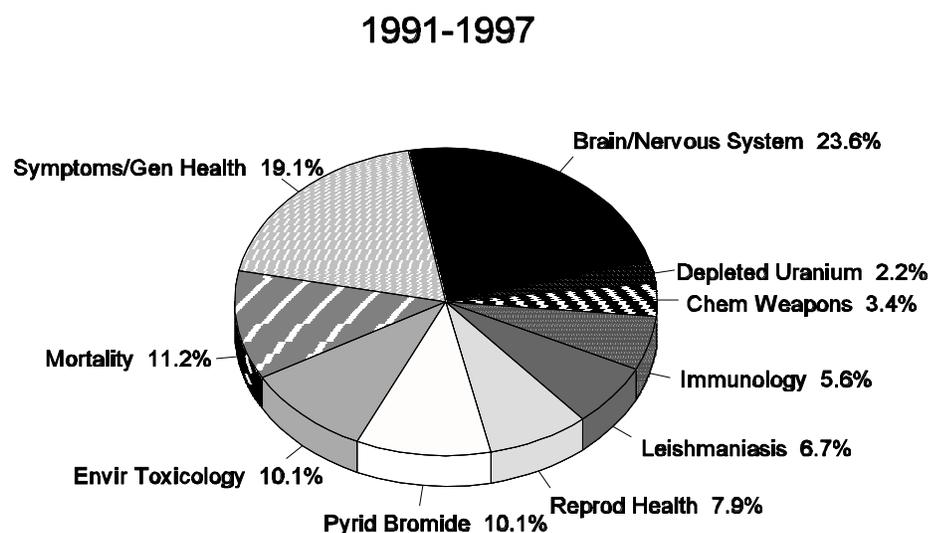


Figure 12. Persian Gulf Illness Research by Study Type and Year



Source: 1997 Annual Report to Congress by the Research Working Group of the Persian Gulf Veterans Coordinating Board

Figure 13. Persian Gulf Illness Research Focus



Source: Research Working Group of the Persian Gulf Veterans Coordinating Board, 1997 Annual Report to Congress

For FY 1997, the DOD allocated almost \$17 million for research on Gulf War veterans' illnesses-related research and solicited proposals in three specific areas: (1) the feasibility of epidemiological studies of troops potentially exposed to chemical warfare agents at the Khamisiyah depot demolition, and basic (animal model) research to assess the potential health effects of exposure to low-levels of chemical weapons; (2) the potential health consequences of exposures to combinations of multiple risk factors; and (3) studies of historical war syndromes and physiological manifestations of stress. DOD awarded \$12 million for new research projects, most of which involved basic science research into health effects of exposure to chemical warfare agents, either alone or in combination with pyridostigmine bromide. DOD also awarded \$1.7 million for studies of historical war syndromes and stress-related illness and \$3.1 million in research funds has been targeted for research into health effects of low-level chemical exposures. A competitive, peer-review grant process was used to fund all of these studies. The Department of Veterans Affairs spent approximately \$2.42 million in direct VA-appropriated funds for Gulf War illness-related research in FY 1997, and this figure is estimated to be \$10.4 million in FY 1998.⁴²¹

CDC is also funding three projects at \$2 million annually for a period of approximately 3 years. The first study will evaluate pulmonary function, occupational and exposure histories, functional status, and risk factors for asthma among a population-based group of Iowa Gulf War veterans and controls. The second will evaluate brain activation patterns, work toward development of a case

definition, and attempt to replicate these findings. A third study will examine the stability of symptoms over time, compare case definitions, and will examine existing definitions (such as for Chronic Fatigue Syndrome) for unexplained illnesses.⁴²²

Gulf War Illnesses Federal Research Funded Outside the Peer Review Process

Although most federal funding is done through a competitive peer review process, DOD has over the years awarded at least \$6.5 million in research grant funding for Gulf War illness projects without such review. An award of \$3.4 million was earmarked in the FY 1995 DOD appropriations bill to fund the research of Dr. Edward Hyman of the Louisiana Medical Foundation in New Orleans. DOD also is in the process of making a smaller grant of approximately \$150,000 to Dr. Garth Nicolson to test his new laboratory methodology to detect *Mycoplasma fermentans*.

In 1997, Dr. Robert Haley of the University of Texas Southwestern Medical Center in Dallas was awarded \$3 million to further investigate his hypothesis that some of the veterans' illnesses may reflect neurotoxicity syndromes resulting from low-level chemical exposures and interactions of exposures. (For a discussion of these studies, please see the consultant reports of Dr. Gerr in Chapter Four and at Appendix II and Dr. Letz in Chapter Four). His initial research had been supported by the Perot Foundation. Dr. Haley and his associates had submitted a grant proposal to DOD for a \$13.8 million three-year, multi-component study. The level of funding that Dr. Haley requested exceeded the \$10 million amount of funding available in the call for proposals in the PGVCB announcement, and the proposal was not recommended for funding by the peer-review panel that evaluated the study.⁴²³ However, in subsequently awarding Dr. Haley \$3 million, DOD stated that it was funding portions of the study that had received favorable ratings from the review panel.⁴²⁴ DOD's decision to fund Dr. Haley outside the competitive peer review process was criticized by the Presidential Advisory Committee on Gulf War Veterans' Illnesses⁴²⁵ and other members of the scientific community. The Institute of Medicine in 1995 and the PAC in its 1996 report both emphasized the importance of external competition in order to ensure the scientific merit, level of priority, and relevance of research proposals. The PAC noted in its 1997 special report that these issues "are especially crucial when spending involves the public's money during times of shrinking budgets; the interests of veterans are not well served by research that is not meritorious."⁴²⁶ The SIU concurs with the PAC and IOM that federal research programs should be guided by sound scientific principles, which is best assured when all research funding is subject to a rigorous and independent peer review process.

Additional Research

Many of the studies that have assessed health outcomes of Gulf War veterans to date are not generalizable to the population of Gulf War veterans and their results may be skewed because they did not use a population-based approach to select study participants. A population-based approach means that all veterans from a defined population of veterans (for example, all Gulf War veterans

from a state or all Gulf War veterans who served in the theater of operations) would be eligible to participate in the study and participants are randomly selected from that group. This approach minimizes biased results and is more likely to ensure results that can be applied to that population as a whole. Further, designing studies to include a similarly selected comparison group of non-deployed Gulf War-era veterans would allow for more reliable comparisons between those who served in the Gulf War and those who did not.⁴²⁷

Although VA is currently in the process of conducting such a population-based study, in doing so it should make every effort to obtain standardized and verified exposure and health outcome data. This study is being conducted through initial telephone interviews and followed up with medical evaluations of 1,000 deployed and 1,000 non-deployed veterans and their immediate family members. The VA study's primary hypothesis is that "Gulf War veterans will have an increased prevalence of the following medical and psychological conditions . . . compared to a control group of non-deployed veterans: chronic fatigue syndrome, fibromyalgia, PTSD, neurological abnormalities, including peripheral neuropathy and cognitive dysfunction, and measures of general health status."⁴²⁸ This study has been planned for several years and will provide important information, but as it is now eight years after the Gulf War all efforts should be made to ensure its timely completion. In addition, large scale population-based studies are underway in the United Kingdom which will examine the rate of health complaints and illnesses among UK servicemembers who served in the Gulf War,⁴²⁹ and to help determine whether there are an increased number of health (including reproductive) problems among the family members of Gulf War veterans. This latter study will examine the full range of reproductive problems and outcomes in random samples of deployed Gulf War veterans and non-deployed Gulf War-era veterans.⁴³⁰ (See the consultant report of Dr. Shanna Swan in Chapter Four and at Appendix LL.)

ALLIED COALITION HEALTH EXPERIENCES

Thirty-eight countries (in addition to the United States) participated in the Allied Coalition force that took part in Operations Desert Storm and Shield.⁴³¹ The SIU sought to learn about their veterans' experience and post-conflict health status because valuable clues might be found to explain why U.S. troops have developed illnesses following the Gulf War. Summaries of the experience of several countries are included at Appendix OO, however, information was not obtained from all 38 countries. Overall, at least three countries (Canada, the Czech Republic, and the United Kingdom) have examined some of their veterans and documented that they have developed health problems similar to U.S. veterans. Interestingly, Egypt, France, Kuwait, and Saudi Arabia state that their Gulf War veteran populations have not developed such health complaints. However, these countries have apparently not systematically examined their Gulf War veteran populations for health problems.

It is beyond the SIU's purview, at this point, to make definitive statements about whether Gulf War veterans from other countries are ill and the reasons why some may not be ill. However, troops

from different countries had have different exposures (e.g., receipt of vaccines or use of PB varied among troops of different countries, although North Atlantic Treaty Organization (NATO) countries gave PB to their troops). In considering health data from other countries, it should also be kept in mind that some countries have national health care systems that provide access to health care for all citizens. Veterans in those countries may be less likely to participate in Gulf War health programs because they already have access to health care. In addition, countries differ in their military pension and disability systems, and most countries do not have a separate veterans' health care system. The SIU believes that additional collaboration with Allied Coalition countries is warranted to further examine the health status of their veterans and to attempt to elucidate reasons why veterans from some countries may not have developed Gulf War undiagnosed-type illnesses.

CONCLUSION

Many veterans have become ill since their service in the Gulf War, and in some instances, they have been disabled by these health problems. The undiagnosed illnesses of many veterans remain poorly understood and as a result, veterans and their families have been appropriately frustrated as they seek answers. However, health problems in the absence of a diagnostic label are very real for the veterans who live with them every day. In addition to the burdens of coping with health problems, some veterans have also been frustrated in their attempts to find appropriate, responsive, and effective care at the Departments of Veterans Affairs and Defense. While these veterans bravely served our country during the Gulf War, our government has not always appropriately served their health care needs during and following that conflict. Many questions still remain about why Gulf War veterans are ill. Some of these questions may never be answered because of shortcomings such as poor data collection and record keeping during the war. However, the common factor in the illnesses among these veterans is their service in the Gulf. Since these illnesses appear to be associated with their service, the most important things that VA and DOD can now do is provide timely, accessible, and appropriate treatment to Gulf War veterans with these illnesses who seek it and attempt to prevent such illnesses in future deployments.

In considering the health problems of Gulf War veterans, inevitable comparisons have been made with post-conflict health problems following other military deployments such as Vietnam and the World Wars. If such adverse health events do indeed follow every conflict, why have DOD and VA not learned more from these events and more effectively intervened to keep history from repeating itself after each deployment? At some point, more comprehensive health policies and programs should be developed that build upon the lessons learned. The same mistakes should not be repeated when the veterans' health and the government's credibility are at stake. DOD and VA share responsibility in anticipating, planning, and preparing for post-deployment health concerns. This continuum of responsibility extends from the beginning of military service and continues with the transition to veteran status through the lifetime of the individual. DOD's responsibilities include the prevention of avoidable illness and injury on the battlefield and a rapid medical response in the field when illnesses or injuries do occur.

DOD and VA are both responsible for providing quality and responsive care for the health concerns that follow any deployment. Greater cooperation and more expedient planning on a regular basis between VA and DOD are needed to adequately address the health concerns that follow military deployments. We cannot afford to wait years after unexplained illnesses have emerged again before initiating a federally coordinated response. Smaller scaled efforts should be initiated as troops are returning home from future deployments to immediately begin assessment and treatment of their health concerns as part of routine DOD and VA health care. Because of the unanswered questions about the illnesses of Gulf War veterans, DOD's and VA's credibility has suffered. In order to restore public trust, it is the responsibility of DOD to demonstrate that it can adequately protect the health of troops and it is the responsibility of both DOD and VA to demonstrate that they can provide quality health care to veterans of any deployment.

RECOMMENDATIONS

1. The Secretary of Defense and Secretary of Veterans Affairs should undertake a major effort to monitor on an ongoing basis the treatment provided to ill Gulf War veterans, especially those with undiagnosed illnesses, to determine whether those veterans are getting better or worse over time. Both agencies should evaluate and revise existing health care programs to remove or minimize barriers to timely and effective veteran participation in them. The Secretary of Defense and Secretary of Veterans Affairs should jointly develop and implement methods to monitor the health status of Gulf War veterans over time to provide early detection of future illnesses which may emerge years later, such as higher rates of cancers.
2. The Assistant Secretary of Defense for Health Affairs, in collaboration with VA and the Department of Health and Human Services, should develop and implement integrated policies and programs that incorporate health lessons learned from the Gulf War, including data collection and retention, surveillance, and protection and monitoring of troop health during deployments.
3. The Secretary of Defense and Secretary of Veterans Affairs should maintain compatible information systems, collect registry information that can be meaningfully analyzed and compared, and implement methods for regular exchange of information on the health status of and effective treatments for Gulf War veterans.
4. The Secretary of Defense should establish a program to improve the capacity for rapid and early detection of exposures that may affect troop health during and after deployments, such as through funding the U.S. Centers for Disease Control and Prevention, to develop technology to rapidly screen persons exposed to a wide range of chemical toxicants, including chemical warfare agents.

5. The Department of Defense, in consultation with the Environmental Protection Agency and the Centers for Disease Control and Prevention, should make available to military commanders environmental intelligence about factors that could adversely affect troop health and thereby impede the successful achievement of military missions.
6. The Secretary of Veterans Affairs should direct that veterans be provided clear and candid information about pertinent environmental health risks they may have experienced during deployments that may have had an adverse impact on their health.
7. The Assistant Secretary of Defense for Health Affairs should develop awareness and treatment doctrine to identify possible troop exposures to depleted uranium (DU) on and off the battlefield and fund research into the health effects of DU exposure. The Departments of Defense and Veterans Affairs should also utilize the existing VA Depleted Uranium Medical Follow-Up Program to provide timely and in-depth medical evaluations to active duty service members and veterans with DU injuries.
8. The Secretary of Defense should direct that complete and accurate medical information is collected and maintained on all troops, from base-line physical examinations to all immunizations and administration of medical products occurring on and off the battlefield. This includes directing that reservists, as well as active duty military personnel, who are deployed receive health assessments before and after deployments.
9. The Secretary of Defense and Secretary of Veterans Affairs should, in collaboration with the national, state-based birth defects registry under development, establish a birth defects registry for all military service members to gather statistics on possible reproductive health effects stemming from battlefield exposures.
10. The Secretary of Defense and Secretary of Veterans Affairs should contract with an independent scientific body to evaluate treatment protocols that have been useful for persons in the general population who suffer from illnesses similar to Gulf War veterans' unexplained illnesses and to recommend funding of appropriate clinical programs and research in this area.
11. The Secretary of Defense and Secretary of Veterans Affairs should only fund Gulf War health research pursuant to an impartial, scientific peer review process, except in the case of the most serious and extreme circumstances.
12. Congress should direct an independent scientific body, such as the National Academy of Sciences, to evaluate the need for and feasibility of a new national center for the study of military health, with an emphasis on post-conflict health concerns and illnesses.