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SUBJECT: Defense Health Board Recommendation Memorandum Pertaining to Psychotropic Medication Prescription Practices and Use and Complementary and Alternative Medicine Use 2011-09

### Reference

Memorandum, Office of the Assistant Secretary of Defense for Health Affairs, 17 August 2010, Question to the Board Requiring Psychotropic Medication Prescription Use and Complementary and Alternative Medicine Use in the Department of Defense

## I. Introduction

The psychological and behavioral effects on Service members of multiple deployments and the mental health impact of serving in the combat settings of Afghanistan and Iraq—dangerous situations for long periods in extreme environments—are ongoing, growing, and urgent national concerns. Exposure to deployment-related stressors is linked to Service members experiencing elevated rates of post-traumatic stress disorder (PTSD), acute anxiety disorder, sleep disturbances, anxiety, depression, and substance abuse disorders. Concerns have been raised about the safety and effectiveness of prescription medication practices for these disorders—on and off label—treatment side effects, medication misuse, polypharmacy (including complementary and alternative medicine [CAM] products), and potential risks and impairments to combat readiness. Questions also have been raised about the following: 1) trends in psychotropic prescription drug use among Service members; 2) the availability of evidence-based practice guidelines for all line personnel encountering Service members in need of psychological health services; and 3) the availability of and access to properly trained mental health personnel in operational settings.

### A. Public Attention to Military Psychological Health Issues

Series of congressional hearings and articles appearing in the media over the past five years have focused on the psychological and behavioral health of the fighting forces, use of psychiatric and pain medications, and access to mental health services. The appropriate metrics to assess concerns about prescription drug use are only partially available.

In May 2006, the *Hartford Courant* published its first in a series of investigative reports on military prescription practices and noted “a growing number of mentally troubled service

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members who are being kept in combat and treated with potent psychotropic medications—a little-examined practice driven in part by a need to maintain troop strength.”<sup>1</sup> The newspaper also reported that antidepressant medications with potentially serious side effects were being dispensed with little or no monitoring and sometimes minimal counseling, despite Food and Drug Administration (FDA) warnings that the drugs can increase suicidal thoughts. The newspaper charged that military doctors treating combat stress symptoms were sending some soldiers back to the front lines after rest and a three-day regimen of medication despite evidence that it typically takes two to six weeks for the prescribed medications to begin working.

A 2010 *Military Times* investigation of electronic records obtained from the Defense Logistics Agency (DLA) concluded that DLA spent \$1.1 billion on psychiatric and pain medications from 2001 to 2009. It also concluded that use of psychiatric medications had increased 76 percent overall during that period, with the use of some medications more than doubling since the start of the current wars.<sup>2</sup> The authors concluded, “at least one in six service members is on some form of psychiatric drug.” The report also asserted that many troops were taking more than one medication, that is, “cocktails” that have been proven safe when used in combination. There also were charges of inappropriate off-label use of prescription drugs.

On March 24, 2010, the U.S. Senate Subcommittee on Personnel, Committee on Armed Services held a hearing to receive testimony on programs and policies related to mental health and psychotropic drug use in the military.<sup>3</sup> The data cited in the *Military Times* articles were introduced, in particular, citing increases in the uses of barbiturates, muscle relaxers, pain relievers, antidepressants, and tranquilizers between 2002 and 2009. During that hearing questions were raised about the reliability and accuracy of those data given the limits of the Pharmacy Data Transaction Service (PDTS) tracking system. Questions also were raised about the sufficiency of supervision and monitoring of clinicians delivering psychological health care.

## **B. Current Stressors**

The Department of Defense (DoD) and its Service members have experienced 10 years of war with multiple risk exposures over extended periods of time. A majority of Service members exhibit significant resilience in the face of these challenges. However, prolonged exposure to stressors—combat-related and otherwise—over repeated deployments can exact a substantial psychological toll on even the most resilient and experienced Service member, as well as on his or her family. It should not be surprising that at this juncture DoD is witnessing an increase in treatment and care given for psychological and behavioral health problems among Service

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<sup>1</sup> Chedekel C and Kauffman M. Special Report: Mentally unfit, forced to fight. *The Hartford Courant*. May 14, 2006.

<sup>2</sup> Tilghman A and McGarry B. Medicating the military: Use of psychiatric drugs has spiked; concerns surface about suicide, other dangers. *Military Times*. March 17, 2010.

<sup>3</sup> U.S. Senate, Subcommittee on Personnel, Committee on Armed Services. Hearing to Receive Testimony on Military Health System Programs, Policies, and Initiatives in Review of the Defense Authorization Request for Fiscal Year 2011 and the Future Years Defense Program, March 24, 2010.

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members and their families. In addition to the heightened fatigue and duress experienced by Service members from combat stressors and deployment, those who care for them also are experiencing burnout and compassion fatigue.

It is worthwhile to note that although psychological health needs must be addressed, unintended consequences can result from greater awareness of psychological health concerns, unintended consequences which DoD must aim to avoid. Better tracking, identification, and treatment can come at the cost of stigmatization of the Service member and his or her family. There have been many efforts, some of which have been successful, to counteract stigma in the military context specifically and in American culture overall.

DoD already has taken many actions to address psychological health issues in military personnel, ranging from requirements for predeployment mental health assessment to policies pertaining to deployment-limiting conditions and medications, to standards for medical fitness. These policies are briefly described in Appendix A. Importantly, DoD also has developed practice guidelines for psychological health conditions, which are based on lessons learned and experiences over the past decade. Some of these practice guidelines were issued after this report was first requested; thus, some needs already have been addressed.

### **C. Charge to the Work Groups/Scope of Analysis**

On August 17, 2010 the Defense Health Board (DHB) received a request from Charles L. Rice, M.D., President, Uniformed Services University of the Health Sciences, Performing the Duties of the Assistant Secretary of Defense for Health Affairs, to review issues and provide guidance surrounding the prescribing and use of psychotropic medications by military personnel. Dr. Rice also requested that DHB review the use of CAM by Service members.

The DHB Co-Vice Presidents established the Psychotropic Medication Work Group and the CAM Work Group, which included a number of Board and Psychological Health External Advisory Subcommittee members. These work groups were later combined to address both issues jointly. Eventually, the combined groups convened during meetings of the DHB Psychological Health Subcommittee.

The questions posed to the group were very broad. With subsequent examination of the assigned tasks, the work group identified the following key areas for review:

- Psychotropic medication and CAM use in deployed and operational settings, and by Service members preparing to deploy, or between deployments
- The most common in-theater psychological health conditions and associated optimal evidence-based therapies that also would be viably deliverable in theater
- The availability of clinically appropriate deployment-related clinical practice guidelines (CPGs)
- Provider scope of practice: Who is providing care and in what context?

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- In-theater treatment processes and protocols used by primary care physicians and psychiatrists prescribing medication
- In-theater availability of medical records for providers, particularly for Army Reserve and National Guard members who may deploy while on psychotropic medication and who may not have received adequate predeployment screening
- The existing framework for knowledge dissemination and awareness of deployment-limiting conditions related to the most common in-theater psychological conditions
- Percentage of Service members deemed non-deployable because of psychological health conditions or experiencing stigma associated with seeking care or challenges related to rejoining their units

Specific issues pertaining to Wounded Warriors coping with physical and psychological comorbidities post-deployment or between deployments also were considered.

Of note, the charge to the work group did not specifically address the use of psychotherapy. The work group noted that psychotherapy is an important and primary treatment option, but is sometimes a challenge in the deployed setting, at least as practiced currently in the civilian sector.

In addition to electronic communications, the work group met on five occasions, holding its first meeting on September 10, 2010, and the last meeting on May 9, 2011. The members received briefings and data from numerous sources within and external to DoD, including the Armed Forces Health Surveillance Center; Service subject matter experts; Walter Reed Army Institute of Research; Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury; National Intrepid Center of Excellence; Force Health Protection and Readiness; DoD Pharmacoeconomic Center; the Combat and Operational Stress Control Training Branch of the Department of Behavioral Health Sciences, Army Medical Department Center and School; University of Maryland Shock Trauma Center; National Center for Complementary and Alternative Medicine at the National Institutes of Health; and the District of Columbia Department of Mental Health. (See Appendix C for a complete list of meetings and briefings.)

An interim report, with preliminary findings and recommendations, was presented to the DHB at its June 14, 2011 meeting. The Board voted to accept the findings and recommendations with some modifications, which are reflected in this—the full report.

## **II. Terminology and Background**

### **A. Psychological, Behavioral, and Mental Health**

“Psychological health” and “behavioral health” are terms most currently in use to supplant the term “mental health.” In practice they are often used interchangeably. The work group uses the term “psychological health” throughout this report to refer to psychological, behavioral, or mental health conditions experienced by Service members during, between, and after deployments.

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## B. Psychotropic Drugs

A psychotropic drug is a chemical substance that crosses the blood-brain barrier and acts primarily on the central nervous system by affecting brain function. Psychotropic drugs can create changes in perception, mood, consciousness, cognition, or behavior. Commonly prescribed psychotropic drugs include antipsychotics, antidepressants, anti-anxiety agents, mood stabilizers, stimulants, and sedative/hypnotics. In addition, many other medications can have psychotropic effects, even if this is not their primary purpose. The work group did not consider the use of medications specific to treating pain, although pain frequently is co-morbid with psychological health disorders (see discussion below).

Prescription drug use—and more specifically, psychotropic prescription drug use—has been steadily increasing in the U.S population. Centers for Disease Control and Prevention (CDC) data from 2010 show that the percentage of the total U.S. population using at least one prescription drug increased from 38 percent in the 1988–1994 period to 48 percent in the years 2005–2008.<sup>4</sup> During the same period, the percentage of all people taking three or more prescription drugs increased from 11 percent to 21 percent. In adults ages 18 to 44, antidepressants are the most commonly prescribed prescription drugs: with use increasing from 1.6 percent in 1988-1994 to 11.9 percent in 2005-2008. Analgesics were the second most prescribed drug, increasing from 7.2 percent to 8.9 percent in the same time periods.

These trends also are found in children and adolescents. Analysis of annual data from the 1996-2007 National Ambulatory Medical Care Surveys found an “increase in the percentage of child visits in which psychotropic medications were prescribed that included at least two psychotropic classes. Across the 12-year period, multiclass psychotropic treatment rose from 14.3% of child psychotropic visits (1996-1999) to 20.2% (2004-2007).”<sup>5</sup> Over that period, “there were significant increases in multiclass psychotropic visits in which ADHD medications, antidepressants, or antipsychotics were prescribed, and a decrease in those visits in which mood stabilizers were prescribed.”<sup>6</sup> There also were increases in co-prescription of ADHD medications and antipsychotic medications and co-prescription of antidepressant and antipsychotic medications.

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<sup>4</sup> National Center for Health Statistics. Health, United States, 2010: With Special Feature on Death and Dying. Hyattsville, MD. 2011.

<sup>5</sup> Comer, JS, Olfson M, Mojtabai R. National trends in child and adolescent psychotropic polypharmacy in office-based practice, 1996-2007. *Journal of the American Academy of Child Psychiatry* 2010 Oct;49(10):1001-1010. Epub 2010 Sep 1. Page 1001.

<sup>6</sup> *Ibid.*, p. 1001.

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A 2009 report by IMS Health<sup>7</sup> shows that antidepressants in the general population were the fourth largest class of prescription drugs dispensed in 2009, up from its fifth place ranking the prior year, with U.S. prescription sales growth of 3 percent to \$9.9 billion. This analysis further demonstrates that psychotropic medications are being more commonly prescribed nationwide.

These increases in the use of psychotropic agents in the general population are likely the result of a number of factors, for example, real or perceived increases in stress and related symptoms, direct marketing to physicians (primarily primary care), direct-to-consumer marketing, increased focus on diagnoses and recognition of disorders, and the time constraints of busy medical practices, which increase the likelihood of a prescription drug being the most expedient form of therapy offered.<sup>8</sup> Thus, the prevalence of psychotropic medicine use among civilians entering the military has most likely been increasing in recent years.

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<sup>7</sup> See

[www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=4e260fc5b45b7210VgnVCM100000ed152ca2RCRD&cpsexcurrchannel=1](http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=4e260fc5b45b7210VgnVCM100000ed152ca2RCRD&cpsexcurrchannel=1).

<sup>8</sup> Schiff GD, Galanter WL. Promoting more conservative prescribing. *Journal of the American Medical Association* 2009; 301(8):865-867.

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### **C. Complementary and Alternative Medicine**

CAM includes medical and health care practices that are traditionally practiced outside the realm of conventional medicine and, in some cases, have not yet been validated using scientific methods. Complementary methods are used along with conventional medical practices while alternative methods are used instead of conventional practices. Integrative methods embrace the best practices of both conventional and complementary medicine as well as whole person care. The traditional CAM domains include four quadrants that include: biologically based practice (e.g., supplements), mind-body medicine (e.g., meditation or spirituality), energy medicine (e.g., light therapy, Reiki, acupuncture), and manipulative and body-based practices (e.g., massage, yoga). Many of these therapies are applied simultaneously.

The most current and comprehensive picture of Americans' use of CAM has been developed through the 2002 and 2007 National Health Interview Surveys (NHIS). From 2002 to 2007, CAM use remained generally constant and relatively high, with approximately 38 percent of American adults reporting use of some form of CAM. The three most commonly used CAM therapies were nonvitamin, nonmineral natural products; deep breathing exercises; and meditation. NHIS data also provided important insights into the reasons for CAM use, which fall into two approximately equal categories: 1) treating a variety of health problems—particularly chronic pain and other symptoms that are difficult to treat, and 2) promoting wellness and prevention.<sup>9</sup>

The 2007 survey also provided extensive data on costs and expenditures. Americans spent \$33.9 billion out-of-pocket for CAM in 2007, accounting for approximately 1.5 percent of total health care expenditures but more than 11 percent of total out-of-pocket health care expenditures. Importantly, about one-third of the total \$33.9 billion was spent on practitioner visits (mostly associated with manipulative and body-based therapies), while nearly two-thirds was spent on a variety of CAM products, classes, and materials not specifically recommended by a health care provider or CAM practitioner (i.e., "self-care"). A total of 44 percent of all out-of-pocket costs for CAM was spent on the purchase of nonvitamin, nonmineral natural products.<sup>10</sup>

### **D. Evidence-Based Versus Evidence-Informed Use of Prescription Drugs (i.e., "on" and "off label" use)**

Different levels of evidence are used to clinically support the use of specific treatments for medical and psychological disorders. One hierarchy adapted by the work group is outlined in Table 1 below. Other frameworks are also available, for example DoD/VA CPGs have used an evidence grading system based on that used by the U.S. Preventive Services Task Force.<sup>11</sup>

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<sup>9</sup> Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Report #12. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007. December 2008.

<sup>10</sup> Ibid.

<sup>11</sup> DoD/VA Clinical Practice Guideline for the Management of Post-Traumatic Stress (2010).

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**Table 1. Levels of Evidence**

Level	Type
1	FDA indication
2	2 positive clinical trials and/or 1 positive meta-analysis
3a	1 positive clinical trial
3b	Expert consensus based on inconclusive trial data, ideally sanctioned through practice guidelines by a professional or scientific organization
4	Preliminary evidence from uncontrolled non-trial research

The highest level of evidence involves an FDA determination that the evidence is sufficient to warrant labeling a drug as indicated for treatment of a specific condition. In most cases, this requires at least two positive, registration-quality, Phase III randomized clinical trials. Although FDA approval is the most stringent criterion, several limitations must be acknowledged. In addition to the trial evidence, it requires initiative by an industry sponsor to submit an application for approval. If the patent for a drug has expired or is within several years of expiration (and thus ready to become generic) and/or the perceived market for the drug is not sufficiently large, the sponsor might not be willing to go through the laborious process of obtaining FDA approval. Also, FDA approval only applies to drugs and devices. This means that nonpharmacological therapies, as well as herbal and natural treatments, do not require FDA approval to be marketed.

Level 2 evidence requires at least two positive clinical trials or a positive meta-analysis synthesizing results from multiple trials. This is superior to one positive trial (Level 3a) because single trials often have limitations and when repeated may not always yield the same results. If only a single positive trial has been published, the strength of evidence can vary depending on the number of subjects in the trial as well as the quality of study design. Expert consensus based on inconclusive trial data is also categorized as Level 3 because it counters the strength of one positive trial with the consideration of expert opinion, the importance of the clinical problem, the evidence for alternative treatments, and current standards of practice. Expert consensus is rated higher if sanctioned by a professional or scientific organization.

In treating patients, it is often desirable to allow the clinician flexibility in providing medications with Levels 1, 2, or 3 evidence for several reasons. First, there may not always be an FDA-approved drug for a particular condition. In this case, acceptance of Level 2 or 3 evidence may be warranted. Second, patients vary in their response to different treatments, and what works in one patient may not work as well in another patient (this is the principle behind “personalized” medicine). For example, although there is no evidence that one antidepressant is more effective than any other antidepressant, the STAR\*D trial showed that individuals not responding to one

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antidepressant may respond to a second or third antidepressant.<sup>12</sup> Third, patients may not tolerate a particular treatment because of side effects or other reasons. In this case, a Level 2 treatment that is effective and tolerable in a particular patient is preferable to a Level 1 treatment that has intolerable side effects. Fourth, treatments can vary widely in their costs, which, although not the overriding factor, must be considered when developing formularies and treatment policies.

#### **E. Polypharmacy**

Polypharmacy is the use of multiple medications by a patient regardless of the route of receipt. It can refer to too many forms of medication or more drugs than are clinically indicated or warranted. It can also refer to situations in which all prescribed medications are clinically indicated but there are too many pills to take (pill burden). Polypharmacy also can result from obtaining drugs from other sources (e.g., friends, families, Internet marketplaces). In some cases of polypharmacy, a portion of the drugs or the combination of drugs may not be evidence based. Polypharmacy can result in increased adverse drug reactions, drug-drug interactions, and higher costs.

However, polypharmacy might be appropriate for patients with complex symptoms or multiple conditions. In the military setting, care has to be taken to ensure that the effects of polypharmacy do not impair readiness. The appropriateness of polypharmacy might differ between civilian and military settings.

### **III. Findings**

#### **A. Prevalence of Psychological and Behavioral Health Problems**

The work group reviewed prevalence data from several sources regarding psychological and behavioral health problems during, between, and after deployments. These data should be considered against the general background risk for psychological health problems. For example, data from the 2008 *Mental Health, United States* survey show that an annual average of 11.2 percent of persons aged 18 or older experienced serious psychological distress in the prior year. Epidemiological surveys estimate that as many as 30 percent of the adult population in the United States meet criteria for a DSM (*Diagnostic and Statistical Manual of Mental Disorders*) diagnosis. For example, a 2005 national survey found that 26.2 percent of adults reported any mental health disorder.<sup>13</sup>

#### **Armed Forces Health Surveillance Center (AFHSC) Data**

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<sup>12</sup> Gaynes B, Warden D, Trivedi M, et al. What did STAR\*D teach us? Results from a large-scale, practical, clinical trial for patients with depression. *Psychiatric Services*. 2009; 60:1439-1445.

<sup>13</sup> Kessler RC, et al. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. *Archives of General Psychiatry*, 2005; 62:617-709.

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AFHSC stores prevalence and treatment data regarding the prevalence and treatment of mental health conditions in Service members before, during, and after deployment. Segmented demographic and individual-level deployment data are received from the Defense Manpower Data Center monthly. In-theater medical encounter data are available through the Theater Medical Data Store (TMDS), and reflect inpatient and outpatient care at Echelon I, II, and III Medical Facilities since May 2008.<sup>14</sup> Although data have been recorded in TMDS since 2003, it was not until 2008 that the dataset was sufficiently robust to use in analyses.

It is difficult to determine what percentage of troops is receiving treatment in theater. Most Service members who receive treatments at a fixed location have access to facilities and providers using the Armed Forces Health Longitudinal Technology Application (AHLTA, the military's electronic health record). Other troops, many of whom are most at risk for psychological health issues, do not receive care at a fixed location because of the operational environment. Little or no retrievable documentation of care is available for these forward-deployed personnel. Also, determination of the population at risk (which would allow for the calculation of prevalence and incidence rates of psychological symptoms, diagnoses, and treatments) is problematic.

AFHSC provided data to the work group on the percent of mental health encounters (of total recorded medical encounters in theater) and the percent of prescriptions (of total prescriptions in theater) given to Service members serving in Operation Iraqi Freedom (OIF) compared to those serving in Operation Enduring Freedom (OEF) between May 1, 2008 and November 30, 2010. Of all mental health encounters recorded in TMDS, 79.0 percent occurred in OIF, compared to 20.2 percent in OEF. Similarly, 81.5 percent of prescriptions for psychotropic drugs were distributed in OIF, compared to 16.7 percent in OEF. The remaining encounters and prescriptions occurred in Operation New Dawn (OND, renamed from OIF on September 1, 2010). These percentages do not represent discrete individuals and it is not uncommon for persons to have more than one encounter or prescription; therefore, the number of encounters and prescriptions are inflated. Data regarding mental health encounters from May 1, 2008 to November 30, 2010, are displayed in Table 2. Data related to mental health encounters, by category, are displayed in Table 3. There are no reliable data prior to 2008.

**Table 2. TMDS Person-Years Deployed, Mental Health Encounters, and Prescriptions by Operation, May 1, 2008 – November 30, 2010**

<b>Operation</b>	<b>Person-Years</b>	<b>Percent Person-Years</b>	<b>Mental Health Encounter Records</b>	<b>Percent of Mental Health Records</b>	<b>Number of Prescription Records</b>	<b>Percent of Prescription Records</b>
OEF	171,910	26.9%	15,297	20.2%	130,325	16.7%

<sup>14</sup> Echelons of care refer to the timing and location of care a Warrior receives following a medical incident, with Echelon I being the first care received, often far forward.

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OIF	460,397	72.1%	59,682	79.0%	634,777	81.5%
OND (September 1, 2010)	6,513	1.0%	602	0.8%	13,986	1.8%
Source: AFHSC, February 24, 2010						

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**Table 3. Counts of Most Common Categories of Mental Health Encounters In Theater (OEF/OIF/OND), May 1, 2008 – November 30, 2010**

Rank	Condition	Encounters			
		2008	2009	2010	Total
1	Tobacco Use Disorder	2,368	5,132	4,421	11,921
2	Anxiety State Unspecified	1,427	2,359	2,796	6,582
3	Depressive Disorder Other	1,564	2,309	2,329	6,202
4	Adjustment Reaction Unspecified	937	1,599	1,865	4,401
5	Brief Depressive Reaction	1,115	1,355	1,415	3,885
6	Disrupted Sleep Wake Cycle	798	1,560	1,408	3,766
7	Persistent Insomnia	857	1,222	1,204	3,283
8	Adjustment Reaction Anxious Mood	679	994	1,153	2,826
9	Adjustment Reaction Mixed Emotion	605	969	1,173	2,747
10	Prolonged Posttraumatic Stress	795	923	1,1013	2,731

Source: AFHSC, February 24, 2010

Medical evacuation data gathered by AFHSC from October 2001 to September 2010 show that “mental disorders” are the fourth highest category of illness, at 11.1 percent, with the most frequent diagnoses in this category being adjustment reactions, mood disorders, and PTSD.<sup>15</sup>

#### **Mental Health Advisory Team Data**

Mental health surveys of deployed troops in OIF and OEF have been conducted periodically starting in 2005. The most recent Mental Health Advisory Team (MHAT) data find that stress levels among Service members in Afghanistan have risen from 6 percent in 2005 to 17.4 percent in 2010. However, mental health staffing has doubled in Afghanistan since 2009, and troops report having better access to care.<sup>16</sup>

Service members on their third or fourth deployment report significantly more acute stress, psychological problems, and among married Service members, significantly more marital problems compared to Soldiers on their first or second deployment. Service members on their third or fourth deployment also reported using medications for psychological or combat stress problems at a significantly higher rate than Service members on their first deployment.

<sup>15</sup> Medical Surveillance Monthly Report. Causes of medical evacuations from Operations Iraqi Freedom (OIF), New Dawn (OND), and Enduring Freedom (OEF), Active and Reserve Components, U.S. Armed Forces, October 2001-September 2010. MSMR 2011; 18(02).

<sup>16</sup> Joint Mental Health Advisory Team (MHAT) 7 Operation Enduring Freedom 2010 Afghanistan. February 22, 2011. Office of the Command Surgeon US Forces Afghanistan (USFOR-A) and Office of The Surgeon General United States Army Medical Command.

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MHAT data for 2009 show that of those Service members who need help with psychological and behavioral health concerns, only about 50 percent seek it, and of those who do, only 42 percent receive it. The primary reasons for not getting help include:

- Stigma (50 percent or more report concerns about this)
- Difficulty getting time off to get help (40 percent)
- Lack of access (40 percent)
- Leader discourages use of mental health services (21 percent).

### **Between Deployments and Post-Deployment Data**

The prevalence of PTSD in troops has been tracked over time. In November 2010 the Walter Reed Army Institute of Research reported to the work group that the baseline prevalence of PTSD in OIF/OEF troops was between 3 percent and 6 percent. Prevalence is higher in infantry post-deployment, at an average of 15 percent. PTSD has high medical and behavioral comorbidity, including depression, anxiety, alcohol abuse, sleep disorders, and relationship problems, as well as injuries such as mild traumatic brain injury (mTBI), concussions, and generalized physical health problems. It is important to note that community-based surveys in civilian populations have shown that persons with PTSD are more likely to report past suicide attempts and ideation.<sup>17</sup>

A 2008 study published by RAND found that 300,000 individuals returning from a forward-deployed status were suffering from PTSD or major depression (as distinguished from depression symptoms).<sup>18</sup> According to the study, in 2007, approximately 53 percent of those who met criteria for PTSD or major depression sought treatment. Approximately 50 percent of those who sought treatment received “minimally adequate treatment (at least eight sessions of psychotherapy or a minimal course of medication).”<sup>19</sup>

It is estimated that between 20 and 30 percent of U.S. military personnel report significant psychological problems after being home 3 to 6 months.<sup>20</sup> Even so, current data suggest that only 4 percent of patients seen in military primary care settings are being prescribed psychotropic medications, in comparison to 5 to 8 percent of primary care patients in the general population.

In practice, most psychological health services are offered in the primary care setting in both theater and garrison settings, in part because of lack of access to mental health specialists and because of the stigma attached to seeking such services. The Army Surgeon General’s Re-Engineering Systems of Primary Care Treatment in the Military (RESPECT-Mil) program is a

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<sup>17</sup> As cited in RAND. 2011. *The War Within: Preventing Suicide in the U.S. Military*

<sup>18</sup> RAND. 2008. *Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery*.

<sup>19</sup> Ibid., p. 108.

<sup>20</sup> Hoge, CW, et al. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *New England Journal of Medicine* 2004;351:13-22.

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model for integrating mental health into primary care treatment. In that program, psychological health screening is offered to all patients, regardless of the reason for their visit. In screening for PTSD, 90 percent screen negative, and of the 10 percent who screen positive, 40 percent are not prescribed medication because they do not meet criteria, and 1.5 percent refuses referral for mental health care.

Many of those who are referred already are receiving psychological health care. Roughly 46 percent of positive screens result in a primary care diagnosis of either depression or possible PTSD, and 26 percent of positive screens result in other behavioral health diagnoses (e.g., adjustment disorders). Of those patients referred to a care manager, 60 percent are taking psychotropic medication(s).

Data presented to the work group from RESPECT-Mil also show that of the 20 percent of Soldiers with moderate to severe psychological health disorders after OIF deployment, 75 percent to 86 percent acknowledged a problem, of which 38 to 45 percent wanted help; of these soldiers who sought assistance, 23 percent to 40 percent visited a primary care professional, while 13 percent to 27 percent visited a mental health professional. OIF returnees with PTSD report twice as many sick calls and missed work days as OIF returnees without PTSD during the year following deployment.

#### **Related or Co-morbid Conditions**

A common misconception is that individuals suffer from two distinctive types of symptom-based conditions: 1) physical conditions, such as pain and sleep disturbances, and 2) psychological conditions, such as depression and PTSD. In reality, physical and psychological conditions frequently overlap: It is more common to encounter an individual with persistent pain who is sleeping poorly and feeling anxious or depressed than someone who has only a single symptom. Additionally, the presence of one symptom can have detrimental effects on other symptoms. Pain can impair sleep and mood, PTSD can aggravate sleep, and pain and poor sleep can increase the cognitive difficulties experienced by individuals with TBI. This overlap and reciprocal influence of symptoms makes a biopsychosocial integrated approach to treatment imperative. It also indicates why attention to the appropriate use of psychotropic medications must simultaneously account for analgesic and sedative-hypnotic use, especially for certain categories (e.g., opioids, benzodiazepines) that have central nervous system effects as well as the potential for addiction and misuse.

#### ***Sleep Disorders***

Population-based research has shown repeatedly that insomnia and sleep disorder are commonly reported symptoms among Service members during and returning from military deployments.<sup>21</sup>

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<sup>21</sup> McLay RN, Klam WP, Volkert SL. Insomnia is the most commonly reported symptom and predicts other symptoms of post-traumatic stress disorder in U.S. service members returning from military deployments. *Military Medicine* 2010; 175(10):759-762.

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Some studies have found sleep problems in 41 percent of those who had been to Iraq or Afghanistan.<sup>22</sup> A 2010 study reported that deployment to Iraq and Afghanistan significantly affects the quality and quantity of sleep of many U.S. military personnel.<sup>23</sup>

The researchers conducted baseline sleep surveys of 41,225 members of the U.S. military before they deployed. Service members who completed a follow-up survey during deployment were 28 percent more likely to say they had trouble falling or staying asleep than those who had not yet been deployed: 30.5 percent versus 25 percent. The research also found that Service members were more than two times more likely to report trouble sleeping if they had baseline symptoms of PTSD or depression, or if they rated their general health as fair or poor. In addition, deployed and post-deployed Service members reported sleeping significantly less than those who had not yet been deployed. Besides its deleterious effect on military fitness, lack of sleep contributes to the development of other psychological problems, such as depression and heightened anxiety.<sup>24</sup>

Sleep disorder is also a symptom of PTSD and acute stress disorder. As discussed further below, data from MHAT 6 show medication for sleep problems at 13.5 percent in support troops and 8.1 percent to 9.2 percent among maneuver personnel. High use of hypnotics to aid in sleep and psychostimulants to stay awake constitutes a high percentage of overall psychotropic drug use in the military population.

Thus, sleep disorders can serve as predictors for other psychological or behavioral health conditions and are a common reason for Service members seeking psychotropic drugs.

### *Pain*

Pain is among the most common problems reported by Service members, a finding that is also true in civilian health care settings. Moreover, pain increases the risk of psychological conditions such as PTSD and depression, and can make such conditions more difficult to treat. The prevalence of pain is a major reason for the prescribing of opioid medications, which, while useful for the short-term treatment of acute pain, should be used cautiously in the treatment of chronic pain where there are safer and potentially more effective alternatives. Finally, any increased use of opioids among Service members must be viewed in context of the increased use of opioid medications in the U.S. population over the past decade.

Based on growing attention to the issue of pain management in military personnel, particularly of the critically wounded in Warrior Transition Units, the Office of The Army Surgeon General conducted a major assessment of pain management in 2010.

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<sup>22</sup> Ibid.

<sup>23</sup> Seelig AD, et al., for the Millennium Cohort Study Team. Sleep patterns before, during, and after deployment to Iraq and Afghanistan. *Sleep* 2010; 33(12):1615-1622.

<sup>24</sup> Eliyahu U, Berlin S, Hadad E, et al. Psychostimulants and military operations. *Military Medicine* 2007; 172(4):383-387.

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Pain is the most frequent reason patients seek physician care in the United States.<sup>25</sup> One of the major components of treatment is use of over-the-counter and prescription medications. Psychoactive drugs such as opioids (e.g., opioid narcotics such as morphine and codeine) are often prescribed to manage pain. This class of drugs can be highly addictive.<sup>26</sup> “According to the Office of National Drug Control Policy, prescription opioid analgesics are the most commonly abused prescription drugs in the United States, with the highest rate of abuse occurring among those ages 18-25.”<sup>27</sup> The Substance Abuse and Mental Health Services Administration estimated that more than 20 million Americans age 12 or older were illicit drug users in 2008.<sup>28</sup>

Drug abuse in the military has paralleled use in the civilian sector. A 2005 Pentagon Health Survey found that 15 percent of Service members admitted to prescription drug abuse in the previous year, with 4 percent in the past month.<sup>29</sup> The 2008 survey reported 22 percent admitting use in the previous year and 13 percent in the previous month. Painkillers are often the drug of choice. TMDS data provided to the work group showed Vicodin<sup>®</sup> to rank eighth in the most commonly prescribed analgesics in theater (17,610 prescriptions between May 2008 and November 2010), which does not necessarily suggest abuse but which should be monitored given the potential for abuse and adverse effects when used in combination with other drugs or alcohol.

In some studies, the prevalence of comorbid PTSD, TBI, and pain exceeds 40 percent in the VA population.<sup>30</sup> In these cases, all conditions need to be treated.

Some individuals seek CAM modalities for pain management, such as acupuncture, yoga therapy, and mindfulness therapy. The National Center for Complementary and Alternative Medicine supports research on the effectiveness of CAM in treating pain, which is variable.<sup>31</sup>

The 2010 Pain Management Task Force wrote that failure to provide consistent and coordinated pain relief to Service members contributes to suicides and prescription drug abuse and complicates cases of mental illness and brain injury.<sup>32</sup> Moreover, the report concluded that prescribing doctors rely too often on narcotic pain relievers, and that there is a “no pain, no gain” culture that encourages troops to ignore injuries until their pain becomes chronic.

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<sup>25</sup> Office of The Army Surgeon General. *Pain Management Task Force, Final Report: Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize the Care for Warrior and Their Families*. May 2010.

<sup>26</sup> Okie S. A flood of opioids, a rising tide of deaths. *New Engl J Med*. 2010; 18;363(21):1981-1985. doi:10.1056/NEJMp1011512.

<sup>27</sup> Ibid., p. E-2. In reference to: Wilson C, Volkow N. Abuse of prescription drugs and the risk of addiction. *Drug and Alcohol Dependence* 2006; 83(1):S4-S7.

<sup>28</sup> SAMSHA National Survey on Drug Use and Health Report, 2008.

<sup>29</sup> 2005 Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel A Component of the Defense Lifestyle Assessment Program (DLAP). December 2006 RTI/7841/106-FR.

<sup>30</sup> Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, 2010.

<sup>31</sup> See: <http://nccam.nih.gov/health/acupuncture/acupuncture-for-pain.htm>.

<sup>32</sup> Office of The Army Surgeon General. *Pain Management Task Force. Final Report May 2010. Providing a Standardized DoD and VHA Vision and Approach to Pain Management to Optimize the Care for Warriors and Their Families*.

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The 2010 Task Force wrote the following:

Many of the Military Health System's (MHS) challenges with pain management are very similar to those faced by other medical systems, but the MHS also faces some unique issues because of its distinctive mission, structure and patient population. For example:

- The nation expects the MHS to provide the highest level of care to those carrying wars' heaviest burdens.
- The transient nature of the military population, including patients and providers, makes continuity of care a challenge for military medicine.
- Pain management challenges associated with combat polytrauma patients require integrated approaches to clinical care that cross traditional medical specialties, not all of which are universally available across the MHS.<sup>33</sup>

The Task Force made a series of recommendations for improved pain management, including the need to "implement a drug abuse assessment strategy to ensure the efficacy of pain treatment and reduce aberrant behavior, abuse and addiction with steroids."<sup>34</sup> The Task Force also recommended screening Service members for risk of substance abuse.

### **Coding Issues Obscure Understanding of Prevalence**

Trying to get an accurate accounting of the prevalence of psychological disorders is confounded by the coding system used across military health operations. Providers, particularly forward-deployed technicians who may diagnose and dispense psychotropic medications, do not always have access to AHLTA, DoD's electronic health record system. In addition, even when there is access to AHLTA, providers may not uniformly code for psychological conditions, including PTSD. For example, V-Codes are used rather than primary International Classification of Diseases, ninth edition, (ICD-9) or DSM-IV diagnoses. The work group was told that clinicians utilize V-Codes to avoid diagnostic codes that may implicate a more serious mental health issue in an environment with ongoing combat. The work group was told, anecdotally, that in some cases, personnel will miscode a diagnosis to protect the Service member from potential stigmatization or discrimination.

### **Findings Regarding Prevalence of Psychological Health Conditions**

1. Because of the unprecedented exposure to stressors resulting from multiple conflicts that span over a decade, Service members and their families are experiencing psychological and behavioral health challenges as a predictable consequence of prolonged and repeated deployments.

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<sup>33</sup> Ibid., p. E-2.

<sup>34</sup> Ibid., p. 57.

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2. Despite these exposures, the majority of military members and their families do not appear to have experienced excessive or disproportionate adverse psychological effects leading them to seek out medical and/or mental health care.
3. The precise prevalence and treatment of psychological health problems among Service members, particularly in theater, is difficult to estimate because of inadequate data collection. Even for clinical interactions coded as mental health visits, there are insufficient and insufficiently comprehensive data describing the treatments or medications prescribed (e.g., individual counseling, psychotherapy/cognitive behavioral therapy, group sessions, medications, and alternative medicine modalities).
4. Efforts are underway across DoD to improve psychological health screening and to foster psychological health and resiliency as assets that need to be developed and sustained. It should be noted that troops are trained for combat, and therefore combat itself is not necessarily an undue stressor.
5. Since 2009 psychological health staffing has doubled and troops have reported better access to care. Nonetheless, improvements can be made in both initial military training and continuing operationally relevant professional development.
6. The importance of sleep problems is reflected in pharmacy data that reveal that sleep medications (such as Ambien<sup>®</sup>) are the predominant prescription psychotropic drug used in theater. Because insomnia (difficulty falling asleep, difficulty sustaining sleep, or inability to restore sleep) is associated with and can lead to comorbid psychological health conditions, it also must be viewed as an operational issue, with line commanders cognizant of the need for sleep hygiene discipline and, as indicated, access to sleep and restoration interventions. The Army Field Manual for Combat Operational Stress Control appropriately focuses on sleep hygiene.
7. Pain is among the most common problems reported by Service members, a finding that is also true in health care settings in the civilian sector. Moreover, pain increases the risk of psychological conditions such as PTSD and depression and can make such conditions more difficult to treat. The prevalence of pain is a major reason for the prescribing of opioid medications. Opioids, which are not in and of themselves psychotropic medications, can be useful for the short-term treatment of acute pain. However, they should be used cautiously in the treatment of chronic pain for which there are safer and potentially more effective alternatives. Finally, any increased use of opioids among Service members must be viewed in context of the seven-fold increase in the use of opioid medications in the U.S. population over the past decade.

**Recommendations Regarding Prevalence of Psychological Health Conditions**

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1. DoD should conduct a comprehensive and systematic review of the prevalence and functional elements of an integrated line and medical model (prevention, self-, "buddy-", and unit-care, field/echelon clinical care delivery) for preventing, detecting, and treating known and predictable psychological conditions in theater. The model should be informed by the 5 to 10 years of psychological health data accumulating from the two most recent conflicts. The Traumatic Events Anxiety Management and Screening (TEAMS) in Deployed Settings "integrated line-medical field and clinical practice guideline" represents important initial progress in this regard.
2. Psychological first aid for predictable combat stress may be best provided at the self- and "buddy-care" levels with enhanced line and leadership training. Peer-to-peer training prior to deployment should augment personal resiliency training as critical preventive and acute treatment measures in collaboration and integration with line initiatives currently underway.
3. DoD should standardize and deploy uniform coding practices for the diagnosis and treatment of psychological health disorders, with particular emphasis on practical in-theater deployment, surveillance, and quality improvement objectives.
4. DoD should incorporate point-of-care guidelines, decision-support tools, and guidance that can be integrated into the medical and mental health care workflow. Embedded decision support in health information technology (e.g., the Armed Forces Health Longitudinal Technology Application [AHLTA]) will improve the provision of best practices and evidence-based care. Training remains essential, particularly for providers in theater who may not have ready access to automated decision support tools.
5. Analogous to the Task Force on Pain, DoD should establish a Task Force on Sleep to identify emerging scientific findings and define best operational and medical practices to optimize performance and readiness.

#### **B. Prescription Drug Data/Prevalence of Use**

Several sources provide some data, albeit limited, on the use of psychotropic medications by military personnel (and, in some, cases, military beneficiaries). In addition to "pills" there are psychotropically active agents in alcohol, energy drinks, and some illicit drugs, which can alter mood and functioning either alone or in combination with pills. There are no fully reliable or comprehensive data on the use of these agents by Service members.<sup>35</sup> In addition, Service members have access to prescription medications and CAM products through a number of sources, not all of which are tracked (see Box A).

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<sup>35</sup> See the *2008 Department of Defense Survey of Health Related Behaviors Among Active Duty Military Personnel* ([www.tricare.mil/2008HealthBehaviors.pdf](http://www.tricare.mil/2008HealthBehaviors.pdf)). This survey found that while use rates for illicit drugs such as marijuana, cocaine, heroin, and meth-amphetamine among Service members has remained very low, overall drug use in recent years has risen sharply. The increase is almost exclusively attributed to a steep rise in the use of prescription drugs, particularly pain relievers.

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**Box A: How Prescription Medications and CAM Products Arrive In-Theater**

- Service members can receive prescription medications in bulk (up to 180 days) before deploying. Prescriptions can be refilled through the TRICARE Mail Order program, which sends prescriptions through the U.S. Postal Service to individual military postal addresses. This method is common for Service members on long deployments.
- Military Treatment Facilities (MTFs) in theater receive bulk drug shipments through routine logistical channels.
- *Service members can bring prescription drugs with them that were obtained through private sector providers.*
- *Service members can order over-the-counter drugs and CAM products online using their own money.*
- *Family and friends stateside can mail drugs and CAM products to Service members at their military postal address.*
- *Service members can purchase some CAM products (botanicals, natural products, supplements) on military installations in theater.*
- *Service members may be dispensed prescriptions drugs by technicians in far forward operational locations where electronic or other recordkeeping might not be available.*
- *Service members may obtain drugs from peers or buddies.*

(The italicized bulleted items are sources for which no reliable data exist.)

The DoD **Pharmacoeconomic Center (PEC)** operates the Prescription Medication Analysis and Reporting Tool (PMART), and the Deployed Prescription Program. The Pharmacy Data Transaction Service (PDTS) is the data source. The PEC mission is to support both the readiness and managed care aspects of the MHS, while promoting an integrated pharmacy benefit. PEC staff includes representatives of the Army, Navy, and Air Force, public health and civilian personnel, as well as physicians, pharmacists, pharmacy technicians, statisticians, data analysts, pharmacoeconomists, customer service representatives, and administrative personnel.

PEC is composed of three components: Clinical Operations, Pharmacy Operations Center (POC), and Pharmacy Outcomes Research Team (PORT). The Clinical Operations staff is charged with evaluating and presenting information on the clinical and cost-effectiveness of drug therapy for the DoD Pharmacy and Therapeutics Committee recommendations. The POC is responsible for implementing the formulary decisions in coordination with the pharmacy contractor, Express Scripts, and the MTF; providing operational and customer support for the DoD pharmacy benefit and users of the pharmacy data system; supporting tools developed for predeployment medication screening; and assisting Warrior Transition Units with medication management and deployment prescriptions. The PORT redefines and refines the predictive models to evaluate impact on beneficiaries and the MHS, improve the outcomes of drug therapy, and enhance the quality of the pharmacy benefit.

PMART was developed by POC in 2001 as a part of the predeployment screening process to assist in monitoring dispensed medications, and identifying medications not available on the

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CENTCOM formulary and over-the-counter and temperature-sensitive medications not available through the mail order pharmacy.

Since 2002, PEC completed more than 557 PMART reports encompassing more than 6.2 million renewable prescriptions for 1.3 million Service members. It found that approximately 23 percent of Service members, including those in Warrior Transition Units, were taking high-risk medications. These medications include those that have the potential for significant therapeutic failure when not provided, or those in combination that may increase risk of adverse effects or when in combination may increase the risk of a Service member in theater. There are also flags in place for medications that are not available on the CENTCOM formulary—drugs considered high-risk, controlled, and needed for chronic disorders.

According to PEC, polypharmacy is defined as the use of four or more unique prescription drugs including a psychotropic medication. Because variability exists in theater regarding access to care and access to medication, psychiatrists and primary health care providers need to be aware of what will be available prior to deployment.

The PMART tool allows health care providers to see medication profile snapshots for deploying Service members and members assigned to Warrior Transition Units. The PMART report is available for all Service members who used TRICARE benefits to fill a prescription (including those filled through mail order, MTFs, and retail pharmacies) and includes information on where a prescription was filled, when it was filled, who filled it, and how many times it was refilled. PMART also has pre-defined and user-defined reports to identify Service members prescribed psychotropics, narcotics, and combinations of medications. PDS has controls in place that capture prescription information from all three points of service and issue clinical warnings, such as therapeutic duplication, drug-drug interactions, and refill inconsistencies. PMART reports are not required but are highly encouraged in the MOD-10 theater guidance to identify individuals who need more attention or a more intensive review.

However, PMART has limitations, for example:

- Not all Reserve and National Guard soldiers use TRICARE as their primary benefit so there are gaps in the prescription information.
- PMART does not currently include in-theater pharmacy data from different levels of care (prescribed or dispensed)
- Individual augmentees do not deploy as part of a unit so they may not be screened
- PEC does not have visibility of illicit or over-the-counter drug use in theater
- Mail order prescriptions may be delivered directly to the Service member and there is no integrated prescription management oversight available in theater
- Not all Service members receive medications through this process; therefore, someone could obtain a double supply of medication in theater because there is no integrated system and PMART does not track in theater prescription information (see Box B).

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**Box B: PMART Activities Prior to Deployment**

- The MTF/BDE or DIV Surgeon/Pharmacy Officer uses a PMART report to pre-screen for medication concerns.
- The MTF/Deployment Tab on the PEC website provides briefing information and theater guidance to Service members on the deployment prescription process.
- Providers prescribe, follow on, or refill medications for deploying Service members using a mail order registration prescription form for access in theater.
- The MTF dispenses up to an initial 180-day supply of medications to treat chronic conditions at the discretion of the provider.

The **Theater Medical Data Store (TMDS)** is a web-based application that tracks collects, analyzes, reports data, and manages care for patients arriving and departing from OIF and OEF. TMDS tracks the location and disposition of ill or injured patients as they move through the echelons of care, from the U.S. Central Command Theater of operations, to Landstuhl Regional Medical Center, and back to selected MHS or VA medical facilities in the United States. It does not track the mail order program or other sources of medication in theater.

TMDS is designed to bring together the different data sources in theater and allows access to various patient treatment data, providing patient visibility and tracking regardless of the service member location. The Armed Forces Health Longitudinal File Theater/Mobile (AHLTA-T/AHLTA-M), the Navy-Shipboard Automated Medical System, the in-patient Composite Health Care System Cache, and the Joint-Patient Tracking Application compile the information in TMDS. The Clinical Data Repository, the Defense Medical Surveillance System, and the Force Health Protection and Readiness system are other data collection systems that receive information from TMDS.

TMDS tracks any medical services delivered in-theater through its database. However, it does not include purchases of medications made by Service members from online retailers or shipped by family members. It is also likely to be missing a fraction of prescriptions not recorded because of a lack of computerized record keeping systems in some deployed environments. TMDS does not include data on indications, off-label use, polypharmacy, mail order prescriptions, or medications received prior to deployment.

**Available Data Regarding Prescription Drug Usage**

Data from TMDS suggest that the overall percentage of Service members who take any psychotropic drug is approximately 4 percent, which has not increased significantly in the last 2.5 years. Meanwhile, there also has been an increase in use of psychotropic medications in the civilian sector, which serves as an important comparison—suggesting that any increase in psychotropic medication use within the military may be a correlate of social and demographic trends in the U.S. population.

**Mental Health Advisory Team (MHAT) 6** data from Brigade Combat units self-reported survey on medication use during deployment (OIF December 2008 – March 2009; OEF April –

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June 2009) show medication for sleep problems at 13.5 percent in support troops and 8.1 to 9.2 percent among maneuver personnel. Medication for mental health or combat stress was 2.9 to 4.8 percent for maneuver personnel, and 5.1 to 6.4 percent for support personnel. The estimate of medication use for sleep during deployment is approximately 11 percent. In comparison, MHAT 5 reported that 17 percent of U.S. Army soldiers used psychological health medications during deployment in Afghanistan, of which half were sleep medications.

Data obtained using the MHS PDTS provides some insight into medication use, despite some limitations. PDTS is an integrated pharmacy system stood up in 2001 and used primarily to communicate patient eligibility and to provide clinical warnings regarding a patient's pharmacy profile across DoD's three points of pharmacy service (MTFs, mail order, and retail network). This allows a provider to review a patient's complete medication history and reduce exposure to unnecessary risks that are present in a non-integrated pharmacy system. These clinical warnings or "soft edits" are returned to pharmacies and MTF providers as notifications for various Prospective Drug Utilization Reviews, which include drug-to-drug Level 1 and 2 interactions based on severity, therapy duplication, and high dose/excessive quantity per the days supply. PDTS also has the ability to restrict patients at the direction of their primary care manager to specific pharmacies, physicians, and doctors if they demonstrate drug-seeking behavior or are considered at risk for harming themselves. PDTS also provides the basis for adjudication of pharmacy claims in the retail point of service.

PDTS does not currently include theater prescription information but through collaboration among the divisions and contractors drug data fields available in in-theater systems have been identified and can be transmitted as usable data elements in PDTS to enhance prescription profile completeness and accuracy. Changes to TMDS are required to include these data fields prospectively and are expected in fourth quarter of 2011.

Because of the requirement to communicate vital patient information among DoD Pharmacy points of service, records are continuously updated based on transaction variables. This update functionality, in many respects, diminishes the utility of PDTS for chronological functions. There are, therefore, limitations associated with trying to use these data in a research or data mining capacity. For example:

1. Patient data elements used to identify Active Duty Service members were not time sensitive prior to April 2007. Therefore, all of a patient's prescriptions filled prior to this date reflect the patient's current status. This underestimates prescription numbers.
2. MTF prescriptions not picked up by the patient at the pharmacy were not marked as prescription non-compliant. This would leave the prescription marked as "active" on the patient's profile even though it was never dispensed.
3. Changes in prescription dispensing procedures, such as day's supply limitations, could affect the figures.
4. The inability to identify prescriptions dispensed for acute use versus chronic use can affect prescription count

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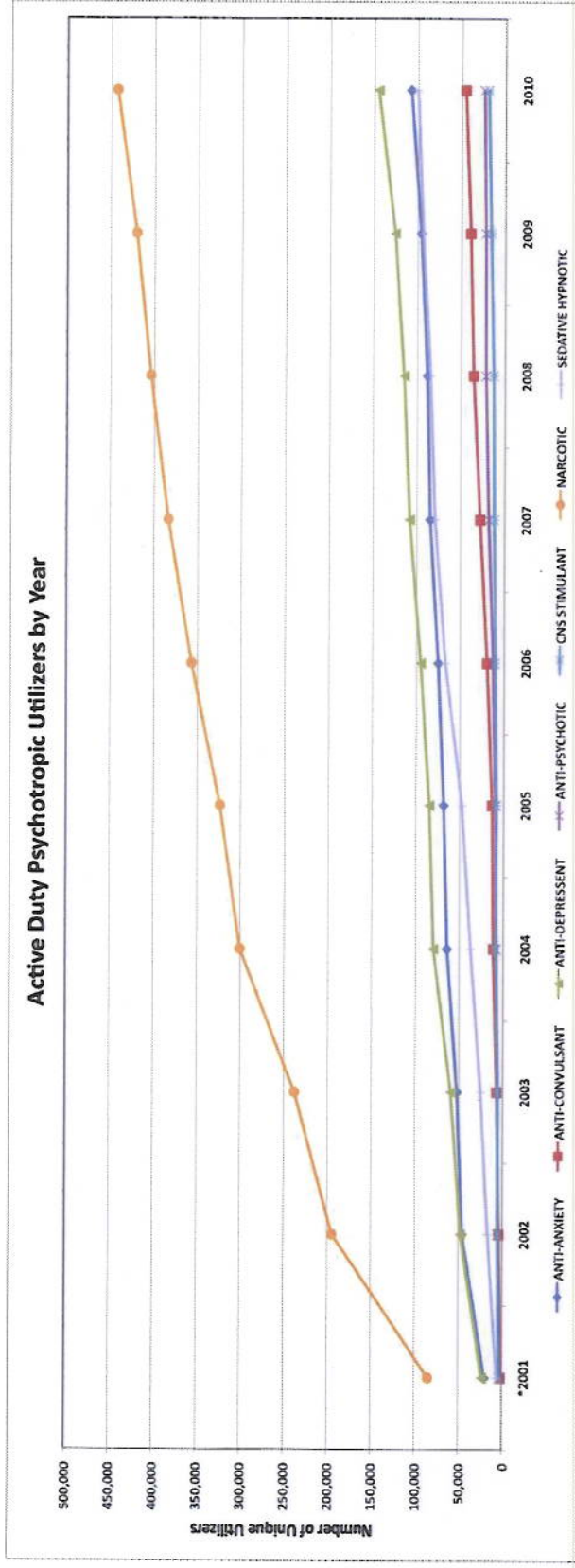
5. The inability to measure prevalence without a denominator of the population within the year cohort affects use estimates.
6. The inability to identify why the prescription drug is being used to include off-label uses diminishes data utility.
7. The mobile population and large unit deployments affect prescription count.

PDTS data support increased use of psychotropic and narcotic medications in the Active Duty population since Fiscal Year 2001 (see Figure 1). Drawing conclusions solely from the MHS prescription database, however, does not provide the complete picture or explain the reasons for increased utilization. It is unclear how much of this use is attributable to a growing beneficiary population, which has increased by 10.8 percent since Fiscal Year 2002; the percentage of utilization attributed to indications other than depression; greater access to behavioral health providers; reduced stigma associated with seeking help; improved efforts to educate Service members, family members, and commanders about behavioral health risk factors; evolving practices in medicine that place more emphasis on psychological health conditions; or the increasing availability of more treatment options in this class of medication. Thus, increased use does not necessarily imply that the Force is sicker.

PDTS data, also show that the overall percentage of Service members taking psychotropic drugs has been relatively low and stable from 2008 to 2010 (see Figure 1).

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1 **Figure 1. Active Duty Psychotropic Utilizers by Year (from PDTS)**  
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Table 4 lists the most commonly prescribed psychotropic medications by Service. Hypnotics (for sleep), antidepressants, and narcotics are more commonly used across the Services. Higher rates of narcotic utilization may be attributed to an increase in orthopedic injuries and other physical conditions precipitated by the wars in Iraq and Afghanistan. PPTS data also show increased use of antidepressant medication in the Active Duty population since Fiscal Year 2004, rising from 4.72 percent of prescriptions in 2004 to 8.70 percent in 2010.

**Table 4. Most Commonly Prescribed Psychotropic Medications (from PPTS)**

Medication	Percent of Enrolled Service Members (Range of Monthly Averages in 2010)			
	Army	Air Force	Navy	Marine Corps
Hypnotics (primarily Ambien, at nearly 50% of psychotropic prescriptions)	2.0 – 2.5	1.32 – 1.64	.79 – 1.07	.79 - .97
Antidepressants	3.46 – 4.28	1.75 – 2.07	1.42 – 2.09	1.41 – 1.89
Anti-anxiety	.96 - 1.13	.81 - .94	.43 - .62	.38 - .52
Narcotic	7.22 – 8.35	4.35 – 5.32	3.61 – 4.17	4.16 – 4.97
Anti-seizure	1.08 – 1.27	.47 - .55	.36 - .56	.41 - .57
Antipsychotic	.58 - .70	.10 - .12	.12 - .25	.22 - .29
Combination (sedative, hypnotic, psychotropic, and narcotic)	.47 - .59	.19 - .25	.12 - .17	.12 - .18

Although PPTS does not currently include in-theater prescription data, theater guidance recommends the maximum use of the mail order pharmacy for chronic medication refills, including antidepressants, which are captured in PPTS.

According to PPTS, the top 10 most frequently dispensed antidepressants represent 95 percent of the utilization among Active Duty Service members in Fiscal Year 2010. These include selective serotonin reuptake inhibitors (i.e., sertraline), trazadone, bupropion, amitriptyline, and duloxetine, which all have other indications and uses.

Antidepressant drugs have many indications and uses for both psychiatric and nonpsychiatric conditions. The psychiatric conditions include, but are not limited to, depression, obsessive-compulsive disorder, panic disorder, PTSD, and seasonal affective disorder. Nonpsychiatric conditions include smoking cessation, a wide variety of neuropathic pain syndromes, “hot flashes,” migraine prophylaxis, TBI, fibromyalgia, and sleep. Notably, tricyclic antidepressants and trazadone are no longer favored for depression, but are widely used for neuropathic pain and insomnia respectively.

When reviewing utilization data, it is important to note the limitations of the data with respect to beneficiary behavior when prescribed a medication in order to correctly interpret the information. Changes made to prescribing patterns also will affect utilization. For example,

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personnel in Warrior Transition Units are often prescribed a 7-day supply of medication at one time rather than a 30-day or 90-day supply, which increases the number of prescriptions but does not give an accurate portrayal of utilization.

Women compared to men appear to be twice as likely to get an antidepressant prescription. From the data, it is unclear if this reflects more depression among women, if women are more likely to seek help or receive more refills, are more likely to receive antidepressants for other reasons, or a combination of factors.

Antidepressant utilization by Active Duty Service members stratified by age showed increased use in all age groups since Fiscal Year 2004, with a trend further upward in Fiscal Year 2008. Active Duty Service members between the ages of 18 and 24 appeared to have the least antidepressant utilization among Service members across all age groups.

Prescription volume among the Services shows that the Army has a steeper upward trend of number of prescriptions per 100,000 Service members. This may reflect the Warrior in Transition population, end-strength numbers, and/or increased frequency of deployments.

#### **Findings Regarding Prevalence of Psychotropic Prescription Drug Use**

1. DoD currently lacks a unified pharmacy database that reflects medication use across predeployment, deployment, and post-deployment settings. Military Health System (MHS) data systems—at the individual, clinical, and population levels—are inadequate to understand and detect important clinical and pharmacy data in a timely fashion. The AHLTA system, as currently functioning, is not sufficiently linked with pharmacy information. The MHS PEC has identified these areas as limiting and is working to identify a data structure for improved in-theater data collection.
2. There has been a trend toward increased use of psychotropic drugs in theater over the past three years.
3. Even given the increased trend, there does not appear to be an inappropriate increase in the use of psychotropic medication given the likely increase in rates of psychological stress. It is likely that the increased use, both in theater and in garrison, reflects appropriate professional judgment and prescribing.
4. Service members can receive medications through multiple routes with varying degrees of documentation. For example, there is inadequate tracking of prescription drugs dispensed at lower echelons of care at forward-deployed locations in theater. Members can also bring medications to theater or receive them through undocumented shipments originating outside the theater.
5. The use of multiple psychotropic medications may be appropriate in select individuals. If evidence-based and appropriately administered, polypharmacy (meaning in this document the

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use of multiple medications, either appropriately or not) can constitute a balanced approach to optimize functioning. Close monitoring of multiple drugs of any type is necessary to both optimize treatment and minimize side effects. However, individual clinical- and population-level MHS data systems do not comprehensively detect polypharmacy, adverse drug-drug interactions, or potential for abuse, particularly in theater. In contrast, surveillance protocols in the civilian sector are used to detect multiple, inappropriate prescribing patterns and protect against drug-drug adverse interactions.

6. Some off-label use of psychotropic medications is appropriate based on available information and evidence. However, DoD lacks a consistent policy or approach to address off-label use of drugs.
7. Although there does not appear to be an inappropriate increase in the use of psychotropic drugs, there may be underuse of alternative treatment strategies, particularly in theater.
8. There is lack of uniform access to medications in theater, across the Services, and across deployed locations. In some cases, unless providers proactively request medications, they may not be readily available at deployed locations.

**Recommendations Regarding Prevalence of Psychotropic Prescription Drug Use**

1. Healthy lifestyles, including proper nutrition, physical activity/exercise, tobacco cessation, avoidance of excessive alcohol use, and effective coping strategies for undue stress should be the foundation of DoD efforts to support resilient responses to operational stressors and psychological health in general. Particular emphasis should be placed on proper sleep hygiene.
2. DoD should review and modify existing policies and practices for capturing, tracking, and monitoring prescription drug data as well as all sources of untracked drugs. In particular:
  - a. prescription drug databases for in-theater operations should better monitor polypharmacy, drug-drug interactions, drug dependence and drug-seeking behaviors;
  - b. polypharmacy should be tracked, assessed, and controlled (when appropriate) through more interoperable and complete data tracking systems; and
  - c. integrated information technology and electronic medical record (EMR) systems (for example, AHLTA) should include embedded decision support and prompts related to psychotropic drug prescribing practices.
3. DoD should review its current guidance regarding the off-label use of certain medications (e.g., Seroquel<sup>®</sup>).
4. DoD should assure that its definition of polypharmacy is consistent with its general use in civilian practice.

**C. Prevalence of CAM Use**

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As noted above, CAM use is widespread and growing in the general population.

An unofficial study found that close to 53 percent of Active Duty personnel and veterans use CAM, in particular herbal therapies. Results suggest that patients who use CAM tend to have higher levels of physical and emotional pain not remedied through conventional medical care. A 2007 study of CAM use among U.S. Navy and Marine Corps personnel found that such therapies are used to treat lower back pain and stress, and to promote weight loss.<sup>36</sup> The authors expressed some concern that “the diet and training regimens of military personnel could be compromised by intake of unconventional supplements and use of unregulated practices that may result in unforeseen health consequences.”

A study published by Jacobson et al. in 2009<sup>37</sup> surveyed CAM use among a large military cohort and found that 30 percent of respondents reported using at least one practitioner-assisted CAM therapy (e.g., massage therapy, chiropractic care), and 27 percent reported using at least one self-administered CAM therapy (e.g., herbal or vitamin treatments, meditation). Those using CAM reported a greater number of comorbidities that might indicate chronic illness management and poorer health.

The 2005 DoD Survey of Health Related Behaviors Among Active Duty Military Personnel found that 60.3 percent of military personnel reported having taken dietary supplements (e.g., vitamins, minerals, antioxidants) at least once a week or more over the prior 12 months. One in four males reported taking a bodybuilding supplement at least once a week in the prior year. Nearly 10 percent of men reported using a performance-enhancing supplement (2.4 percent of women reported use).

Researchers at the Samueli Institute have reported that “there are now medical providers within the military medical system that are practicing commonly accepted modalities such as acupuncture.”<sup>38</sup> The 2011 VA/DoD Clinical Practice Guideline for Management of Post Traumatic Stress (discussed further below) states there is insufficient evidence to recommend CAM approaches as first-line treatments for PTSD, although CAM approaches that facilitate relaxation responses (e.g., mindfulness, yoga, acupuncture, massage) may be considered for adjunctive treatment of hyperarousal symptoms.

There is growing research evidence facilitating the development of guidelines that compare the use and effectiveness of certain CAM modalities for depression (see Appendix B).

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<sup>36</sup> Smith T, Ryan M, Smith B, et al. Complementary and alternative medicine use among U.S. Navy and Marine Corps personnel. *Biomedical Central Complementary and Alternative Medicine*, 2007; 7(16): 1-9.

<sup>37</sup> Jacobson IG, et al. Self-reported health symptoms and conditions among complementary and alternative medicine users in a large military cohort. Naval Health Research Center, Report No. 08-43.

<sup>38</sup> McPherson F, Schwenka M. Use of complementary and alternative therapies among active duty soldiers, military retirees, and family members at a military hospital. *Military Medicine*. 2004; 169(5): 354-357

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### **Findings Regarding CAM**

1. There is growing evidence of the effectiveness of some CAM modalities, in particular acupuncture, mindfulness, and a selected few oral agents for treating pain and psychological conditions such as depression. These interventions may be a practical alternative treatment choice or an adjunct to prescription medications.
2. CAM modalities are not a covered benefit under TRICARE despite some being available in varying degrees at multiple MTFs.

### **Recommendations Regarding CAM**

1. DoD should conduct and support military-relevant studies to measure the effectiveness of CAM approaches for the management of common psychological symptoms versus psychotropic medications for conditions with high prevalence and/or operational impacts.
2. Just as it encourages the use of public health and psychological consultants, though called by different names across the Services, DoD should encourage the Services to create CAM-consultancies.
3. As an example of covered benefits reflecting current evidence-based practice, DoD should ensure that any CAM treatments that are recommended in its CPGs are part of the TRICARE benefit, and that uniformed providers are trained in these techniques.

### **D. Clinical Practice Guidelines**

DoD and VA define CPGs as:

Recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach that includes: Determination of appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction; and a literature review to determine the strength of the evidence in relation to these criteria. (2010 DoD/VA Clinical Practice Guideline for Post-Deployment Health Evaluation and Management)

The intents of the guideline are to:

- Reduce current unwarranted practice variation and provide facilities with a structured framework to help improve patient outcomes
- Provide evidence-based recommendations to assist providers and their patients in the decisionmaking process
- Identify outcome measures to support the development of practice-based evidence that can ultimately be used to improve clinical guidelines.

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Several DOD and/or VA practice guidelines focusing on psychological health issues have been developed.

In 2000-2001, DoD and VA jointly developed the **Clinical Practice Guideline for Post-Deployment Health Evaluation and Management**. The guideline was developed to assist clinicians in primary care settings in determining specific diagnoses for individuals seeking care for potentially deployment related experiences or exposures. It provides a structure, clinical tools, and linked resources allowing clinicians to evaluate and manage patients with deployment-related health concerns. The guideline also applies to nondeployed individuals who are experiencing health concerns related to a deployment, such as family members of recently deployed personnel. The guideline is evidence-based, when possible.

The 2006 **Army Field Manual for Combat and Operational Stress Control (FM 4-02.51) (FM 8-51)** provides detailed doctrinal guidance for controlling excessive stress in combat and other operational environments. It provides a useful model of stress for operational purposes. It identifies command and leadership responsibilities for combat and operational stress control (COSC) as well as consultation, training, and education assistance available to units. It also provides guidance to behavioral health personnel and combat stress control and identifies the requirements for COSC consultation, planning, coordination, rehearsal, and implementation of a COSC plan. The manual emphasizes that "Sound leadership works to keep stressors within tolerable limits and prepares the troops mentally and physically to endure them. Some of the most potent stressors can be due to personal organizational problems in the unit or on the home front. These, too, must be identified and, when possible, corrected or controlled." (p. viii) The Field Manual includes specific information on the identification of combat stress and a step-response section to inform treatment using self-/buddy-unit- interventions and it emphasizes the need to integrate with a medical personnel practice guideline for treatment in an operational setting.

The 2009 **VA/DoD Clinical Practice Guideline for Management of Major Depressive Disorder (MDD)** focuses on adult patients with MDD. It is relevant to all health care professionals who have direct contact with patients with MDD, and who make decisions about their care. This version of the guideline was specifically tailored to what would be of greatest value to the primary care provider. It contains guidance for screening and diagnosis, pharmacological and talk-based treatment, monitoring, and patient education.

The 2009 **VA/DoD Clinical Practice Guideline for Management of Substance Use Disorders** applies to adult patients with substance use conditions treated in any VA/DoD clinical setting, including patients who have both substance use and other health conditions; and patients with any level of severity of use ranging from hazardous and problematic use to substance use disorders. It contains algorithms for screening and initial assessment, management, addiction-focused pharmacotherapy, and stabilization and withdrawal management.

Most recently, the 2010 update of the **Clinical Practice Guideline for the Management of Post-Traumatic Stress** was developed under the auspices of the Veterans Health Administration

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and DoD, pursuant to directives from VA. This 2010 VA/DoD guideline update builds on the 2004 VA/DoD **Clinical Practice Guideline for the Management of Post-Traumatic Stress**. This guideline is relevant to all health care professionals providing or directing treatment services for patients with post-traumatic stress at any VA/DoD healthcare setting. The most important goal of the guideline:

“...is to provide scientific evidence-based practice evaluations and interventions. The guideline was developed to assist facilities in implementing processes of care that are evidence-based and designed to achieve maximum functionality and independence, as well as improve patient and family quality of life. The related specifics are:

- To identify the critical decision points in the management of patients with post-traumatic stress disorder
- To allow flexibility so that local policies or procedures, such as those regarding referrals to or consultation with specialty care (mental healthcare), can be accommodated
- To decrease the development of complications and co-morbidity
- To improve patient outcomes—i.e., reduce symptoms, decrease co-morbidity, increase functional status, and enhance the quality of life.” (p. 6)

Importantly, this guideline provides information about the evidence base for not only traditional psychological health therapies, such as medication and cognitive behavioral therapy, but also for CAM modalities.

As a point of comparison, the **Tactical Combat Casualty Care (TC<sup>3</sup>)** model might be emulated in the area of psychological health, particularly given the unique and very prevalent stressors inherent in multiple deployments in the Global War on Terror. The TC<sup>3</sup> effort originated in 1996 with the goal of improving combat trauma outcomes through optimization of the care provided in the tactical prehospital environment. The aim was to combine good tactics with good medicine. The Tri-Service Command on TC<sup>3</sup> was stood up in 2001 as a U.S. Special Operations Command biomedical research effort to ensure that emerging technology and information is incorporated in TC<sup>3</sup> guidelines on an ongoing basis. In 2007, the Command was realigned at the direction of the Assistant Secretary of Defense for Health Affairs to function as a subgroup of the Trauma and Injury Subcommittee of the DHB. The standardized approach used by the TC<sup>3</sup> involves 1) aggressive surveillance in theatre for survival and complications of trauma 2) rapid convening of subject matter experts to review potential improvements to current therapy and guidelines 3) design of operational changes to improve outcomes 4) real-time or short cycle time analysis of results of intervention and 5) peer reviewed literature publication of the results of intervention.

### **Findings Regarding Clinical Practice Guidelines**

1. DoD has initiated some promising integrated line and medical protocols for identifying and rapidly addressing psychological health issues in theater (e.g., TEAMS).

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2. The 2010 VA/DoD Clinical Practice Guideline for Management of Post-Traumatic Stress is a significant contribution to improving acute psychological health services for Service members. The guideline describes the critical decision points in case management and provides clear and comprehensive evidence-based recommendations incorporating current information and practices for practitioners to appropriately administer psychotropic medications, psychotherapy, and CAM throughout DoD and VA health care systems. However, a systematic means to evaluate and readjust the guideline's practicability and usefulness in theater does not appear to be in place.
3. It is uncertain how well disseminated and implemented current CPGs are; how the CPGs are generated and updated systematically, including their alignment with line policy and programs; or how they create a uniform approach to identifying and managing common operational stress reactions in the deployed setting.
4. Provider training alone is insufficient for ensuring that CPGs are deployed and utilized appropriately. Policy, line and in-field systems and support are required to insure optimization of care, effective treatment, and return of troops to operational effectiveness.

#### **Recommendations Regarding Clinical Practice Guidelines**

1. Better integration of line and medical approaches to the identification and treatment of combat stress disorders with uniform guidance and implementation is necessary across the Services.
2. In-context descriptions of appropriate clinical pathways for common psychological health issues should be made available at the point of care, for example, in the current or developing EMR system.
3. DoD should prioritize its research and practice guidelines so that they are evidence informed regarding psychological health practices as they are actually conducted in applied field operations and garrison care. This should include the systematic application of quality improvement techniques. The Department should also develop a framework for gathering data about the effectiveness and utility of all interventions, rapid dissemination of these data, and rapid turnaround in the application of those data to care. A useful, though not perfectly analogous, model for this is Tactical Combat Casualty Care.

#### **E. Personnel and Training Issues**

Primary care physicians and to some degree, medical technicians provide the majority of psychological health care in-theater rather than psychiatrists or psychologists. This is especially true for initial identification and management, and often is appropriate. Chaplains also play an important role in psychological health support. Educating general medical providers about common psychological symptoms, complications, and treatment is critical for early intervention

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as well as ongoing treatment management. Data regarding appropriate psychological treatment in theater are scarce.

The Marine Corps is sending more mental health teams to the front lines, with the goal of better treating an emotionally strained force.<sup>39</sup> **Operational Stress Control and Readiness** teams (OSCAR) were to be expanded to include the battalion level, putting mental health support services closer to combat troops. A mobile care team of Navy Medicine mental health professionals is currently deployed to Afghanistan, conducting mental health surveillance, command consultation, and coordinating mental health care for sailors throughout the Area of Operational Responsibility.

At its November 3, 2010 meeting CAPT Edward Simmer, Executive Officer, Naval Hospital Beaufort, reported to the work group that the Navy is committed to exploring efforts that would integrate mental health care with primary care by training primary care physicians to recognize and treat psychiatric morbidities and integrate mental health providers into primary care clinics. He noted that one goal of OSCAR is to assign a mental health provider to large USMC units prior to deployment to increase the providers' and Marines' level of comfort and decrease the stigma associated with seeking care for mental health issues. OSCAR providers also spend a significant amount of time performing outreach with Marines, rather than waiting for Marines to come to a traditional mental health clinic setting, further reducing barriers to care.

At the December 2, 2010 meeting, CAPT Simmer reviewed the training, regulation and supervision practices for Independent Duty Corpsmen (IDCs) who prescribe medications. IDCs receive significant additional training compared to general duty corpsmen. Every two years, IDCs must undergo a review and recertification with a licensed medical provider to demonstrate that they are still able to perform their duties safely. Although IDCs are not permitted to prescribe psychotropic medications routinely, they may occasionally do so in an emergency situation. Additionally, there is a seven-page list of medications IDCs are permitted to prescribe, many of which have psychotropic effects.

**The Defense Centers of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury** is focusing on health care provider resilience in the deployed setting. Efforts are underway to develop a deployment model with recovery and sustainment guidance for health care providers comparable to that provided to the combat support components, based on the Total Force Fitness Model.<sup>40</sup> DCoE has integrated evidence-based domains and variables that are important for resilience into the military demand resource model to create a balanced workload for providers, who are susceptible to "compassion fatigue."

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<sup>39</sup> March 2010 Senate hearing, VADM Adam M. Robinson, Jr., USN, Surgeon General of the United States Navy, and Chief, Navy Bureau of Medicine and Surgery.

<sup>40</sup> Jones W, O'Connor F, Deuster P, et al. (Guest Editors). Total Force Fitness for the 21<sup>st</sup> Century: A New Paradigm. *Military Medicine International Journal of AMSUS*. 2010, 175:8. Supplement.

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The **Center for Deployment Psychology** (Uniformed Services University of the Health Sciences) is designed to train both military and civilian mental health care providers to better care for service members. The center provides a two-week training course five times a year, a portion of which addresses how mental health care providers can remain functioning.

The **Combat Operational Stress Control (COSC)** Training branch and the Department of Behavioral Health Sciences at the **Army Medical Department Center and School** provide 25 functional courses updated biannually to correspond with lessons learned from the field. Tri-Service behavioral health providers who have attended courses include psychiatrists, psychologists, occupational therapists, nurses, medical technicians, and social workers. The Behavioral Health Campaign plan focuses on delivering information to the field on the assessment and management of substance use disorders, MDD, PTSD, suicide, and risk management in a primary care setting.

COSC training is required for deploying uniformed providers, although the evidence-based treatment modalities are optional for behavioral health providers. As larger reserve units are deploying, Mobile Training Teams deliver training at home stations in the mobilization window. The course aims to familiarize nonprescribers with the symptoms, side effects, and drug interactions that could be found in theater and enable them to effectively assess the situation and recommend a referral. The operational context of the theater can be challenging for nonprescribers who must answer questions for providers regarding referrals. The training does not address CAM modalities but does focus on alternative methods of treatment prior to medication (e.g., relaxation and sleep hygiene).

#### **Findings Regarding Personnel and Training**

1. In recent years, DoD has increased the number and quality of trained psychological and behavioral health personnel and training for primary care providers and members of the chaplain corps in psychological health. However, available education and training opportunities are not standardized, either across Services or disciplines.

#### **Recommendations Regarding Personnel and Training**

1. Basic training courses for all providers should include integrated protocols for managing combat stress reactions and related comorbidities, including content on line leadership and unit practices, self-care, psychotropic medications, psychotherapy, and effective CAM modalities.
2. Professional competencies must be initially assessed, periodically reassessed, consistently maintained, and updated to reflect best evidence, and continued professional supervision should be available. Specific training with defined, specialty-specific (e.g. unit medic, medical technician, primary care provider, psychologist, psychiatrist, social worker, clinical case manager) scope of practice for the treatment of psychological conditions in theater should be developed, deployed, and updated, as appropriate, based on new evidence derived

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from civilian and military focused operational studies. DoD should optimize the use of existing educational tools, teletechnologies, and mobile applications for training all levels of care providers for PTSD and other psychological conditions.

3. DoD should develop web-based self-management tools and strategies to educate and guide Service members and families on evidence-based treatment alternatives for chronic problems, such as sleep and pain.

#### IV. The Way Ahead

Prolonged combat and multiple deployments can increase the risk of psychological distress. This should be prevented when possible, rapidly identified and accurately diagnosed, and treated appropriately. A comprehensive effort is required to reduce stigma and recognize the whole person, not just his or her symptoms.

It is important to recognize that the use of psychotropic medication for the treatment of some psychological health symptoms is clinically appropriate and necessary, and should not be considered a problem when carefully prescribed and monitored. This is particularly true in the context of a comprehensive, patient-centric approach to maintaining function and operational effectiveness.

The DHB urges attention to the following key issues in the future:

- 1) DoD must continue to assess, recognize, and decrease the very real stigma associated with psychological health conditions.
- 2) DoD must continue to recognize the generally decreased access to military medical and mental health expertise, policy, and best practices in the Guard and Reserve Component.
- 3) DoD and VA must continue to improve communication and systems integration to ensure that the prevalence of psychological conditions and the treatment of military members are better described and optimized, particularly for long periods following deployments and conclusion of active service.

The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:



Nancy Dickey, M.D.  
DHB President

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## **Appendix A DoD/Service Policies**

A. In November 2006, the Assistant Secretary of Defense issued **“Policy Guidance for Deployment-Limiting Psychiatric Conditions and Medications.”** in partial satisfaction of requirements established by Section 738 of the National Defense Authorization Act for Fiscal Year 2007 (P.L. 109-364). It pertains to deployment and continued service in a deployed environment for military personnel who experience psychiatric disorders and/or who are prescribed psychotropic drugs. In sum, the guidance sets time limits for treatment and restoration to full functioning, and establishes policies for conditions disqualifying for deployment. It states “the availability, accessibility, and practicality of a course of treatment or continuation of treatment in theater should be consistent with practice standards.” Most relevant it lists deployment limitations associated with psychotropic medication, noting that the prescribing of some medications needs to be done in consideration of the operational environment. It also notes “psychotropic medications may be prescribed for a variety of conditions that are not assigned a psychiatric diagnosis.” Medications that are inherently disqualifying for deployment include:

- antipsychotics used to control psychotic, bipolar, and chronic insomnia symptoms; lithium and anticonvulsants to control bipolar symptoms;
- those requiring special storage considerations, such as refrigeration;
- those requiring laboratory monitoring or special assessments, including lithium, anticonvulsants, and antipsychotics;
- those prescribed within three months prior to deployment that have yet to demonstrate efficacy of be free from significantly impairing side effects.

The Guidance also prescribes procedures for assessments and documentation of limitations throughout the military lifecycle process of sustainment, pre-deployment, deployment, and post-deployment periods. Medical readiness assessments are conducted in the sustainment period through the Periodic Health Assessment (PHA), the Post-Deployment Health Reassessment (PDHRA), and routine healthcare visits.

B. In February 2010, DoD issued an Instruction, **“Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees,”**<sup>41</sup> with the purpose of assigning responsibilities and providing procedures for ensuring that Service members and DoD civilian employees are medically able to accomplish their duties in deployed environments. It sets medical standards regarding assessments and conditions for waivers. The following mental health disorders are listed as “usually precluding contingency deployment:

- Psychotic and/or bipolar disorders
- Psychiatric disorders under treatment with fewer than three months of demonstrated stability

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<sup>41</sup> DoD Instruction Number 6490.07. February 5, 2010.

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- Clinical psychiatric disorders with residual symptoms that impair duty performance
- Mental health conditions that pose a substantial risk for deterioration and/or recurrence of impairing symptoms in the deployed environment
- Chronic medical conditions that require ongoing treatment with antipsychotics, lithium, or anticonvulsants.

The policy assigns responsibility to the Chairman of the Joint Chiefs of Staff to establish a minimum standard when developing medical requirements for entering the theater of operations and implementing a medical requirements waiver process that includes waiver computerization and archival storage. It assigns responsibility to Combatant Commanders to establish a process for reviewing recommendations from the Services regarding the granting of exceptions to medical standards (waivers), including a mechanism to track and archive all approved or denied waivers and the medical conditions requiring the waivers.

C. In July 2010, the Office of the Assistant Secretary for Defense issued a memorandum **“Mental Health Assessments for Members of the Armed Forces Deployed in Connection with a Contingency Operation”** in response to a requirement of the NDAA for Fiscal Year 2010, Section 708 to implement person-to-person mental health assessments for each member of the Armed Forces who is deployed in connection with a contingency operation. The memorandum prescribes the intervals for assessments and references training and guidance for health care providers performing the assessments. The memorandum instructed the Assistant Secretaries of the Army, Navy, and Air Force, and the Director Joint Staff to provide implementation plans. It specifies who can perform these mental health assessments. It also states that assessment results must be recorded in the Service member’s medical record to assist with health surveillance of the deploying force and to allow sharing of mental health assessment data with providers from VA.

D. DoD has issued **Standards of Medical Fitness, Rapid Action Revision, 23 August 2010** (Army Regulation 40–501) that state the following:

- (a) A psychiatric condition controlled by medication should not automatically lead to non-deployment. Soldiers with a psychiatric disorder in remission or whose residual symptoms do not impair duty performance may be considered for deployment duties. The commander makes the ultimate decision to deploy after consulting with the treating physician or other privileged provider. The availability, accessibility, and practicality of a course of treatment or continuation of treatment in theater or austere environment should be consistent with clinical practice standards. If there are any questions on the safety of psychiatric medication, a psychiatrist must be consulted.
- (b) Psychotic and bipolar disorders are considered disqualifying for deployment.
- (c) Psychiatric disorders that meet medical retention standards must demonstrate a pattern of stability without significant symptoms for at least 3 months prior to deployment.
- (d) Soldiers must demonstrate behavioral stability and minimal potential for deterioration or recurrence of symptoms in a deployed, austere environment, to the extent this can be predicted.

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The potential for deterioration must be evaluated considering potential environmental demands and individual vulnerabilities.

The standards reiterate the medication disqualifying for deployment that appear in the “**Policy Guidance for Deployment-Limiting Psychiatric Conditions and Medications.**” They also state “Decisions to deploy personnel on such medications should be balanced with necessity for such medication in order to effectively function in a deployed setting, susceptibility to withdrawal symptoms, ability to secure and procure controlled medications, and potential for medication abuse.”

E. According to the “**CENTCOM Surgeon Policy for Psychotropic Medications (MOD 10)**”:

- Follow-up care and refill/new prescriptions will need to be written by a provider in-theater to ensure close monitoring
- Renewal prescriptions will be filled entirely in theater for a new (up to) 180-day supply, at which point the patient will need to be seen again for another new prescription
- If a service member on a psychotropic medication is stable and has enough medication on hand, the theater provider may send a new prescription to the POC
- The SRP site is responsible for telling deploying service members what they must do:
- Obtain a refill for psychotropic medications while in-theater
- If prescriptions are being written for anti-seizure medications but used for other indications than mood control, providers must write the indication on the Mail Order registration/prescription form
- The POC will process refills through the Mail Order for these medications

In addition, the CENTCOM Surgeon remains the approval authority for Behavioral Health waiver requests.

F. A recent **Headquarters, Department of the Army Executive Order (HQDA EXORD)** mandates screening points and the use of a Down Range Assessment Tool and directs Army-wide support to Medical Command (MEDCOM) implementation. These orders were directed both to medical personnel and line units to provide a screening tool that measures how soldiers are coping and if they are ready for redeployment or reintegration.

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**Appendix B**  
**Comparison of Guidelines on Complementary and Alternative Medicine (CAM) Therapies for Depression**

CAM Therapy	Is there evidence of efficacy? <sup>a</sup>							SIGN <sup>d</sup>	Dosage and Other Comments
	APA <sup>b</sup>		CANMAT <sup>c</sup>		Adjunct therapy	Adjunct therapy	SIGN <sup>d</sup>		
	Mono-therapy	Adjunct therapy	Mono-therapy	Adjunct therapy					
Nutraceuticals/herbal									
St. John's wort	Yes	No	Yes	No	No	Yes	Yes	600-1800 mg/day. Risks include great variability in dose of various extracts and drug interactions	
SAME	Yes	No	Yes	No	No	Maybe	Maybe	Oral dose typically 800-1600 mg per day.	
Omega-3 fatty acids	Maybe	Yes	Yes	Yes	Yes	No	No	1-2 gm/day of EPA. Need more research on optimal dose; preferred formulation (EPA vs. EPA+DHA); equivalency of fish intake vs. capsules	
Folic acid	No	Maybe	No	Maybe	Maybe	No	No	1-2 mg/day	
Other									
Acupuncture	No	No	No	No	No	No	No	Better evidence for pain to date than for depression.	
Exercise	Maybe	Maybe	No	Maybe	Maybe	Yes	Yes	Unclear if there are differences in the degree of benefit related to the type and dose of exercise.	
Yoga	--	--	No	Maybe	Maybe	No	No	Blinding has been a problem in trials to date.	
Mindfulness-based therapies	Maybe	No	--	--	--	Maybe	Maybe	Some trials have combined with cognitive behavioral therapy; often done as a group therapy.	
Light therapy	Yes	Maybe	Yes	No	No	Maybe	Maybe	10,000 lux, 30 min each morning. Evidence best as monotherapy for seasonal depression. Some evidence as adjunct therapy for	



## Complementary and Alternative Medicine Therapies for Depression

### Nutritional and herbal therapies

The nutritional and herbal supplements most commonly studied for depression are hypericum extract (St. John's wort), S-adenosyl-L-methionine (SAME), polyunsaturated omega-3 fatty acids, and folic acid. The Table summarizes the evidence-based recommendations from panels in the United States, Canada, and Scotland.

- **St. John's wort.** Despite evidence of modest efficacy for St. John's wort in mild to moderate depression, you should be cautious about its use. There is no standardized dose and there is a risk of interactions with several common medications, including oral contraceptives.

- **SAMe.** SAMe is a synthetic form of a dietary amino acid, which is thought to function as a methyl donor in many biological processes involving neurotransmitters. Several meta-analyses have shown a moderate effect of SAMe as monotherapy for depression, with less evidence supporting its use to augment standard depression therapies. SAMe is usually well-tolerated. Reported adverse effects include: GI symptoms, dry mouth, headache, vertigo, insomnia, tachycardia, and restlessness.

- **Omega-3 fatty acids.** Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are long-chain omega-3 fatty acids found in fish and marine sources. Adding omega-3-fatty acids may improve treatment response to antidepressants and may be useful during pregnancy, when many women stop taking antidepressants. Omega-3-fatty acids may be obtained by eating fish, such as herring, salmon, tuna, sardines, mackerel, trout, oysters, and halibut, at least two times a week or taking EPA+DHA supplements. Note that EPA may be more effective for depression, and doses over 3 grams daily may have a significant anticoagulant effect.

- **Folic acid.** Low levels of folic acid have been associated with increased risk of depression and poor response to treatment. This deficiency may be caused by medications, such as oral contraceptives and anticonvulsants, as well as alcohol and tobacco use. Other causes of low levels of folic acid include: malabsorption conditions, pregnancy, emotional stress, oxidative stress, and diseases causing cellular proliferation, such as leukemia. In addition, some medications, such as lamotrigine, metformin, sulfasalazine, triamterene, and methotrexate, may inhibit transformation of folate to the neuroactive L-methylfolate form. Adding folic acid, folic acid, and L-methylfolate (the neuroactive form) to a patient's regimen may improve treatment response in patients with folate deficiencies. Dietary sources include leafy vegetables, legumes, fruits, fortified cereals, and breads. L-methylfolate (7.5-15 mg daily) may be more effective for use in treatment-resistant depression, regardless of folic acid levels.

- **Other supplements.** Evidence is inadequate to support the use of inositol, tryptophan, and DHEA for depression treatment. Nor is there good evidence for the use of chromium, ginseng, ginkgo biloba, glutamine, or selenium as monotherapy for depression. A few agents may play a role in selected patients. For example, low vitamin D levels have been associated with mood disorders in some studies. Supplementing vitamin D3 (at least 800 IU daily) may improve depressive symptoms, especially seasonal. Note that vitamin D3 is best absorbed when taken with a fatty meal. Testosterone restoration may be beneficial for men with low testosterone levels and partial response to antidepressants. Adding estrogen may be beneficial for perimenopausal women with depression. However, all of these need more research.

### Other nonmedicinal treatment options

- *Exercise* may play a role in preventing depression, and it may be helpful as adjunctive therapy for mild to moderate depression.
- *Sleep deprivation* can have immediate but short-lived antidepressant effects, especially in bipolar depression, but it can trigger mania. Although sleep deprivation can improve mood rapidly, relapse usually occurs after a recovery sleep.
- *Phototherapy*, also called light therapy, may be effective as monotherapy for seasonal affective disorder, and it may produce some benefits for nonseasonal depression when combined with pharmacotherapy. Phototherapy involves daily exposure to 10,000 lux for 30 to 60 minutes. Response may occur within days. Be aware, however, that excessive exposure may trigger mania. Phototherapy may be useful during pregnancy, when many women choose not to use antidepressants. Dawn simulators may also be effective adjuncts.
- *Yoga and mindfulness-based therapies* have been promising in some trials; however, more research is needed.

### References for Appendix B

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- Scottish Intercollegiate Guidelines Network (SIGN). Non-pharmaceutical management of depression in adults: a national clinical guideline. January 2010. [www.sign.ac.uk](http://www.sign.ac.uk).

## Appendix C Meetings and Briefings

**November 3, 2010**

Arlington, Virginia

Captain Edward Simmer, Executive Officer, Naval Hospital Beaufort.

Presentation: *Questions to the Board: Scope and Priority Areas.*

*Service Psychiatrist Panel*

Captain Edward Simmer, Executive Officer, Naval Hospital Beaufort.

Major Joshua Morganstein, Psychiatry Department Chief, Addiction Services Element, JointBase Andrews.

Major Joseph Villacis, Acting Psychiatry Consultant to the U.S. Air Force.

Colonel John Stasinos, Addiction Medicine Consultant, Office of the Surgeon General, Army.

Dr. Charles Hoge, U.S. Army Colonel (Ret.), Walter Reed Army Institute of Research.

Presentation: *Post-Traumatic Stress Disorder Treatment in Military Populations: Presentation to the Defense Health Board.*

Dr. Nisha Money, Chief, Integrative and Holistic Health, Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE). Presentation: *Complementary and Alternative Medicine (CAM) and Mind-Body Integrative Health Skills for Total Force Fitness: An Overview, Its Use, and the Effects on Prevention, Readiness, and Resilience.*

Captain Robert Koffman, Deputy Director for Clinical Operations, National Intrepid Center of Excellence (NICoE). Presentation: *In-Theater Psychiatric Care: Meeting the Needs of the Navy Individual Augmentee: The Mobile Care Team.*

Commander Meena Vythilingam, Deputy Director, Psychological Health Strategic Operations, Force Health Protection and Readiness (FHP&R), Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)). Presentation: *Psychotropic Prescriptions In-Theater: 2.5 Years of Data from the Department of Defense (DoD) Theater Medical Data Store.*

**December 2-3, 2010**

Rockville, Maryland

With the Defense Health Board (DHB) Psychological Health External Advisory Subcommittee

Lieutenant Colonel Stacia Spridgen, Director, Pharmacoeconomic Center (PEC), DoD.

Presentation: *DoD PEC.*

Dr. Brian Berman, Director, Center for Integrative Medicine, University of Maryland School of Medicine. Presentation: *Evidence-Based Use of CAM for Pain Management and Integration of Approaches and Therapies in Patient Care.*

Captain Edward Simmer, Executive Officer, Naval Hospital Beaufort. Presentation: *Training, Regulation and Supervision of Corpsmen Who Prescribe Psychotropic Medications.*

Dr. Mark Bates, Director, Resilience and Prevention Directorate, DCoE. Presentation: *DCoE Initiatives Regarding Deployment Psychological Health Issues and Provider Training.*

Dr. Josephine Briggs, Director, National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health. Presentation: *NCCAM: Evidence-Based CAM.*

Dr. Elspeth Cameron Ritchie, Chief Clinical Officer, District of Columbia Department of Mental Health. Presentation: *In-Theater Psychotropic Medication Use and Military Operational Considerations.*

Colonel Rebecca Porter, Chief, Behavioral Health Division, Office of the Surgeon General, Army. Presentation: *Overview of Current Efforts Towards Enhancing Behavioral Health Care and Support for Service Members and Their Families: Comprehensive Behavioral Health System of Care.*

Carl Smith, Chief, Combat and Operational Stress Control (COSC) Training Branch, Department of Behavioral Health Sciences, Army Medical Department Center and School. Presentation: *Army COSC Course Curriculum for Psychotropic Medication.*

Commander Meena Vythilingam, Deputy Director, Psychological Health Strategic Operations, FHP&R, OASD(HA). Presentation: *Psychotropic Prescriptions In-Theater: 2.5 Years of Data from the DoD Theater Medical Data Store.*

**February 24-25, 2011**

Bethesda, Maryland

With the DHB Psychological Health External Advisory Subcommittee

Dr. Michael Dinneen, Director, Office of Strategy Management, Health Affairs. Presentation: *Psychological Health Working Group: Setting the Strategic Direction to Improve Outcomes.*

Colonel Christopher Robinson, Deputy Director: Psychological Health, DCoE. Presentation: *Overview of DCoE.*

Colonel Charles Engel, Director, Deployment Health Clinical Center, DCoE. Presentation: *The Army Re-Engineering Systems of Primary Care Treatment in the Military Program: Rationale, Concept, Implementation, Outcomes & Future Challenges.*

Colonel Robert DeFrait, Director, Armed Forces Health Surveillance Center (AFHSC). Presentation: *AFHSC Capabilities for Evaluation of Prescription Medication Use.*

**May 9, 2011**

Bethesda, Maryland

DHB Psychological Health External Advisory Subcommittee

*Discussion of Draft DHB Psychotropic Medication and CAM Report*

Psychological Health External Advisory Subcommittee members, invited guests, and Service psychiatrist representatives.