

Final Program Review
Sleep Disorders in Gulf War Veterans
VA Boston Healthcare System

1. RESPONSIVENESS TO INITIAL PROPOSAL

a. 2020 GW veterans returned the initial sleep health questionnaire, 936 in VISN 1 and 1084 in the comparison VISN. Despite small differences in the two groups, their responses were similar. GW veterans continue to have high rates of symptoms suggestive of sleep disorders. Of these 66% met eligibility criteria to qualify for a sleep disorders evaluation. We projected evaluating 300 GW veterans with surveys indicating high risk for a sleep disorder in our sleep disorders evaluation program. During the 18 months of actual enrollment, 134 veterans participated in Gulf War SLEEP. There was a high rate of sleep disorders in these participants, 97% were diagnosed with an existing sleep disorder. This indicates the VA medical center Gulf War population provides a large enough pool to give adequate sample size.

b. We were able to track utilization of VA services using the Outpatient Clinic Files (OPC). These are national data files containing electronic records of all inpatient and outpatient utilization at all VA medical facilities. We were able to identify which veterans were current users of DVA services. Fifty-one% of those participating were not current VA users. We demonstrated that a Sleep Evaluation Program similar to GW SLEEP could attract veterans not currently using VA facilities.

c. Our primary assessment tool was the sleep health questionnaire which utilized questions from the National Health Survey of Gulf War Era Veterans questionnaire currently being given to GW veterans as well as questions from several previously validated questionnaires; the Epworth Sleepiness Scale and the Modified Hawaii Sleep Questionnaire. The sleep health questionnaire was given pre and post intervention to both treatment groups. The components of the sleep health questionnaire as well as the SF-12 Quality of Life scale and the VA Customer Satisfaction survey provide ample measures for quantitatively demonstrating study outcomes.

d. Patient satisfaction and functional status were determined using VA's national customer satisfaction survey form "1998 About Your VA Clinic Visits" and the SF-12 (modified for veterans) respectively at the beginning of the study and end of the study. Because we used a rolling enrollment period over the course of 18 months, the time between pre and post surveys was, on average, 7 months.

e. All positions were filled as proposed in grant proposal. The proposal was approved by the Institutional Review Board of our Medical Centers.

2. SCIENTIFIC MERIT

a. We compared the sleep health questionnaire responses of veterans VISN 1 to those of the comparison VISN. The two groups showed similar high levels of sleep-related complaints. Followup survey results were compared between those who underwent

evaluation and treatment and those in the comparison VISN who met entry criteria but received no intervention.

b. The large number of respondents to the initial survey provided sufficient power to detect differences between the two VISNs. The smaller than expected number of participants in the evaluation and treatment program may reduce the likelihood of showing a treatment response.

c. The study meets requirements for good clinical study design. Several conclusions can be drawn about the persistence of sleep-related symptoms in the GW veterans population. Conclusions on the best treatment methods will require further study.

3. RELEVANCE TO GULF WAR VETERANS' HEALTH

Preliminary results from our project show that our methods for screening and evaluating for sleep disorders can attract GW veterans not currently using DVA facilities and identify unrecognized sleep disorders. We established criteria for identifying GW veterans with sleep disorders using the ongoing National Health Survey of Gulf War Era Veterans questionnaire. The high rate of veterans meeting these criteria highlights the need for the DVA to provide sleep medicine services. Participation in this program resulted in a significant improvement in the veterans quality of life, however, further research into the most effective method for treating sleep disorders in this population is still needed.

4. INNOVATION

We demonstrated that an outreach program utilizing a case-manager directed multi-disciplinary treatment group could successfully identify and attract GW veterans with ongoing complaints due to unrecognized sleep disorders. This program proved successful in attracting GW veterans not currently using the DVA and in improving the quality of life of those participating in the program.

Report Date: 9/30/00

DETAIL SUMMARY SHEET

TITLE: Sleep Disorders in Gulf War Veterans

KEYWORDS: Sleep disorders, Persian Gulf Syndrome, sleep apnea, insomnia

PRINCIPAL INVESTIGATOR: Lawrence Epstein, M.D.

CO-INVESTIGATORS: Daniel Gottlieb, M.D., Robert Brown, M.D., Eric Garshick, M.D., Sigmund Hough, M.D.

VA SITE: West Roxbury VAMC
Boston VAMC
Brockton VAMC

STATUS: Ongoing
 Complete

APPROVAL DATE: 7/8/98
REVIEW DATE: 9/30/00

FUNDING: Current FY: 246,375

Total: \$696,000

STUDY OBJECTIVE:

Objective 1: Reduce symptoms and improve the quality of life of GW veterans by increasing recognition and treatment of existing sleep disorders.

Objective 2: Utilization of a multidisciplinary specialized treatment unit featuring case managers will lead to high GW veteran satisfaction with Department of Veterans Affairs (DVA) services.

TECHNICAL APPROACH:

1. Mail survey to identify GW veterans with symptoms suggestive of sleep disorders.
2. Recruit eligible GW veterans to undergo sleep medicine evaluation
3. Identify and treat any present sleep disorders
4. Evaluate effect of treatment on presenting symptoms and customer satisfaction
5. Compare treatment group with nonintervention group

There was no change from the original protocol except reduction of time to follow-up mail survey from 1 year to 6 months. This change was necessitated by the fixed duration of the project and a longer than expected recruitment period.

FINDINGS:

1. Identification of nonintervention group.
 Identified VISN with comparable:
 - 1) Customer Satisfaction ratings, 2) mix of DVA facilities, and 3) demographics.

2. Mail Survey:
 - a. Initial survey completed using modified Dillman method
 1. 48% response rate (2020 surveys)
 2. 66% of responders are eligible to participate
 3. 21% of eligible veterans willing to participate
 4. 134 veterans evaluated
 - b. Similar responses to survey in treatment and nonintervention groups

3. Evaluation and Treatment Phase (Gulf War SLEEP)
 - a. Multi- Center Study
 1. Brockton/West Roxbury VAMC: 94/134 patients (70%)
 2. Boston VAMC: 40/134 patients (30%)

 - b. Utilization pattern
 1. Current users of DVA: 66/134 (49%)
 2. Previous nonusers of DVA: 68/134 (51%)

 - c. Sleep Disorders Prevalence
 1. High rate of treatable sleep disorders found: 114/118 patients who completed evaluation (97%)
 2. Distribution of sleep diagnoses:

Diagnosis	Frequency	Percent
Obstructive Sleep Apnea	49	41.5
Primary Insomnia	13	11.0
Insomnia due to Psychiatric or Psychologic disorders	26	22.0
Circadian Rhythm Disorder	10	8.5
Insufficient Sleep Syndrome	10	8.5
Restless Legs Syndrome/Periodic Limb Movement Disorder	4	3.4
Other Sleep Disorders	2	1.7
None	4	3.4

4. Follow-up Survey

a. Identical survey sent to participants in Gulf War SLEEP and all eligible veterans in the nonintervention group 6 months following the initial survey

b. Response rate:

1. Gulf War SLEEP 74/134 (55%) (not all responses mailed/received yet)
2. Nonintervention group 419/707 (59%)

c. Longitudinal changes

Gulf War SLEEP participants had a statistically significant improvement in quality of life scores compared to the nonintervention group-

	GW SLEEP		Nonintervention Group		p Value
	Baseline	Follow-up	Baseline	Follow-up	Between Groups
Sleep Survey Score	7.37	6.72 *	6.44	5.94*	0.57
Customer Satisfaction	0.3054	0.2127*	0.3678	0.3177*	0.14
SF-12 Physical	35.5	35.7	39.2	39.3	0.91
SF-12 Mental	36.8	41.5*	40.8	41.0	0.0003

* stastically significant improvement within group (from baseline to 6 month follow-up)

5. Adverse reactions: None.

CONCLUSIONS:

1. There is a high rate of undiagnosed sleep disorders in Gulf War Veterans
2. The sleep disorders found in these veterans have previously been well characterized and are treatable. In this cohort, participation in the program resulted in an improvement in quality of life.
3. Screening measures currently in use successfully identify GW veterans with sleep disorders.
4. The availability of Sleep Medicine services increases GW veterans' utilization of DVA facilities.

It is impractical and expensive to establish fully staffed sleep laboratories in each VAMC within a given VISN.

The willingness of GW veterans to come to a specialized treatment center successfully demonstrates the efficacy of establishing a multidisciplinary Sleep Medicine Program to address the concerns of GW veterans. The high rate of undetected sleep disorders indicates it is also essential to increase awareness of sleep disorders at all DVA facilities.

FY00 FINAL REVIEW OF RESEARCH

INSTRUCTIONS: Please answer the following questions and sign at the bottom of the page. Give an explanation for all negative responses.

YES NO

- 1. Research files are being maintained by the principal investigator.
- 2. These files are ready to be inspected as part of the continuing/periodic review process as required by VHA and other federal regulations.
- 3. If human use, subject participation or risk has not been influenced by new developments or literature.
- 4. If human use, the current risk/benefit ratio is about the same (or lower) as when the study was first approved.
- 5. If human use, I have reviewed the consent form during this report period to ensure its appropriateness (give date of review: _____).
The consent form has been revised and updated, if required, to meet HUC / IRB guidelines

This was a clinical program with no experimental treatments, therefore a consent form was not required. The overall program was reviewed and approved by the IRB prior to the start of the project.

Lawrence Epstein, M.D.
Signature

9/30/00
Date

PROVIDE A COPY OF THE CURRENT CONSENT FORM AND, IF REQUIRED, A COPY OF THE REVISED / UPDATED VERSION.

Report Date 9/30/00

FY 00 LIST OF PUBLICATIONS

- (Pr) Presentations:
Epstein, L. Identification and Management of Sleep Disorders in Gulf War Veterans. Conference on Federally Sponsored Gulf War Veterans' Illnesses Research. Pentagon City, VA, June 25, 1999