UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

FEB - 2 2018

The Honorable Thad Cochran
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to section 725(f)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which required the Secretary of Defense to support a series of chiropractic clinical trials by the National Institutes of Health or an independent academic institution. The Department submitted the initial reports on each of the three clinical trials: Assessment of Chiropractic Treatment (ACT), in 2011 (ACT 1), and 2013 (ACTs 2 and 3), respectively. All three clinical trials are led by the RAND Corporation and its collaborators (the Naval Medical Center San Diego, the Walter Reed National Military Medical Center, the Naval Hospital Pensacola, the Palmer Center for Chiropractic Research and the Samueli Institute). The last report sent to Congress on July 28, 2016, promised this final report on ACT 1 trial in December 2017, ACT 2 in April 2018, and ACT 3 in December 2018. However, due to delays with clinical trial results and recruiting patients, ACT 2 and ACT 3 reports will be delayed. The plan is to submit the final reports for ACT 2 in June 2018 and ACT 3 in September 2019.

The RAND Corporation, along with collaborating institutions Palmer College of Chiropractic and Samueli Institute, was awarded $7.5M for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel," or ACT. Three clinical trials were planned, the initial clinical trial (ACT 1), and two additional clinical trials (ACT 2 and ACT 3, respectively). This report details the results of ACT 1. The ACT 1 trial results align with results seen in trials with non-military populations and support chiropractic care as a safe and modestly effective treatment to be considered in treatment of lower back pain.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

Robert L. Wilkie

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

FEB - 2 2018

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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Sincerely,

Robert L. Wilkie

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

FEB - 2 2018

Dear Mr. Chairman:

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Sincerely,

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

The Honorable Kay Granger
Chairwoman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

FEB - 2 2018

Dear Madam Chairwoman:

The enclosed report is in response to section 725(f)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which required the Secretary of Defense to support a series of chiropractic clinical trials by the National Institutes of Health or an independent academic institution. The Department submitted the initial reports on each of the three clinical trials: Assessment of Chiropractic Treatment (ACT), in 2011 (ACT 1), and 2013 (ACTs 2 and 3), respectively. All three clinical trials are led by the RAND Corporation and its collaborators (the Naval Medical Center San Diego, the Walter Reed National Military Medical Center, the Naval Hospital Pensacola, the Palmer Center for Chiropractic Research and the Samueli Institute). The last report sent to Congress on July 28, 2016, promised this final report on ACT 1 trial in December 2017, ACT 2 in April 2018, and ACT 3 in December 2018. However, due to delays with clinical trial results and recruiting patients, ACT 2 and ACT 3 reports will be delayed. The plan is to submit the final reports for ACT 2 in June 2018 and ACT 3 in September 2019.

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Sincerely,

Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

REPORT TO CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO SECTION 725(f)(2) OF THE NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2010 (PUBLIC LAW 111–84)

"CHIROPRACTIC CLINICAL TRIALS"

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

The estimated cost of this report or study for the Department of Defense is approximately $8,100 in Fiscal Years 2016 - 2017. This includes $7,370 in expenses and $740 in DoD labor.
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BACKGROUND

Since 1985, the Department of Defense (DoD) has conducted several demonstration projects designed to examine the cost and feasibility of chiropractic healthcare services for its beneficiaries. The results of these projects have generally concluded that it is feasible to implement chiropractic services as a military healthcare benefit, and the resulting patient satisfaction is higher than that seen with traditional medical care.[1, 2] Following results of the demonstration projects, the Floyd D. Spence National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2001 (Public Law 106-398) requested that the DoD develop and implement a plan to make a chiropractic benefit available to all Active Duty personnel in the U.S. Armed Forces. The resulting Chiropractic Care Program established chiropractic care to Active Duty Service members at 49 military clinics and hospitals, and later expanded care to a total of 60 locations by the NDAA for FY 2009 (Public Law 110-417). Currently, chiropractic care is offered at a total of 66 military clinics and hospitals.[3] At this time, the service is not available at the remaining Military Health System (MHS) healthcare facilities, nor is it available to all MHS healthcare beneficiaries. Chiropractic care is only available to Active Duty Service members and activated Guard/Reserve members.

The NDAA for FY 2010 (Public Law 111-84) provided for additional research on the outcomes of chiropractic treatment in the MHS, while continuing the chiropractic benefit available at select MHS facilities. The legislation required the Secretary of Defense provide for the conduct of chiropractic clinical trials, in accordance with the requirements of section 725. In May 2010, the Chiropractic Clinical Trials requirement was assigned by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to the U.S. Army Medical Research and Materiel Command and to the Congressionally Directed Medical Research Programs (CDMRP) for execution.

The CDMRP initiated the execution of the NDAA for FY 2010 Chiropractic Clinical Trials requirement in accordance with its accepted execution management processes. The ASD(HA) allocated a total of $7.5 million (M) from FY 2010 Defense Health Program funds to support the Chiropractic Clinical Trials. A program announcement was released by the CDMRP on May 12, 2010, and full proposal receipt occurred in August 2010. The responses were externally peer reviewed by subject matter experts in chiropractic care, chiropractic research, and musculoskeletal research, as well as consumer representatives (military Service members with orthopedic conditions who utilized chiropractic care). Funding recommendations were made in September 2010 by a programmatic review panel composed of the Joint Program Committee Chairs from the Military Operational Medicine Research Program, Combat Casualty Care Research Program, and Clinical and Rehabilitative Medicine Research Program, a representative from the Office of the Surgeon General, a representative from the Office of the ASD(HA), a chiropractic practitioner within the DoD, and a consumer representative. One proposal was recommended for funding, and the award was issued in February 2011, as detailed below.

The RAND Corporation, along with collaborating institutions Palmer College of Chiropractic and Samueli Institute, was awarded $7.5M for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel," or ACT. The ACT is a multi-institutional effort with several military sites, and

is designed to carry out the following objectives: (1a) Compare pain and functional outcomes of chiropractic manipulation therapy plus usual medical care (UMC) to UMC alone in a randomized, controlled trial of Active Duty military personnel ages 18-50 years with non-surgical acute, sub-acute, or chronic low back pain; (1b) Measure and compare changes in smoking behavior after participation in a smoking cessation program offered with chiropractic manipulation therapy plus UMC or with UMC alone; (2) Assess the effect of chiropractic manipulation therapy on military readiness, by comparing pre- and post-treatment differences in reflexes and reaction times in Special Operations Forces; (3) Determine differences in strength, balance, and likelihood of re-injury between combat-ready troops receiving either chiropractic manipulation therapy or sham manipulation.

Three clinical trials were planned, with objectives 1a and 1b addressed in an initial clinical trial (ACT 1), and two additional clinical trials planned for objectives 2 and 3 (ACT 2 and ACT 3, respectively). This report details the results of ACT 1, the first chiropractic clinical trial to be completed. ACT 2 and ACT 3 are currently ongoing, with estimated completion dates of June 2018 and September 2019, respectively.

ACT 1 INTRODUCTION

Low back pain (LBP) is one of the leading causes of disability, healthcare costs, and lost work productivity globally. Furthermore, it is one of the most common reasons Service members seek medical care, and is a leading cause of medical evacuation from combat theaters.[4] Many treatment options exist for LBP, but there is little consensus on which treatment is optimal for specific patients, and effectiveness is often limited. Treatment options include lower-risk intervention approaches such as education and self-management, exercise, physical therapy, and over-the-counter pain medications, and higher-risk approaches such as injections, anti-depressants, narcotics, and surgery.

Many patients turn to alternative treatments such as chiropractic care or acupuncture to augment or replace more traditional therapies. Chiropractic care, or spinal manipulation (the primary therapeutic procedure performed during chiropractic care), is one of the more common alternative treatments for LBP, and several clinical studies have been conducted in civilian populations to evaluate its effectiveness.[5] However, the practice has not been well studied in military populations. To address this gap, the ACT 1 study team conducted a trial to investigate the effectiveness of the addition of chiropractic care to UMC in Active Duty military personnel with LBP. The study team sought to test the hypothesis that Active Duty military personnel with LBP who are treated with chiropractic care and UMC will show a greater reduction in pain and disability than those receiving UMC alone.

ACT 1 METHODS

ACT 1 was designed as a pragmatic, prospective, multi-site, parallel group comparative effectiveness trial, and was conducted at three military sites: Walter Reed National Military Medical Center (WRNMMC), Naval Hospital Pensacola (NHP), and Naval Medical Center San Diego (NMCSD). All participants were Active Duty personnel aged 18-50 years with acute,

subacute, or chronic LBP. Exclusion criteria included recent spinal fracture, spinal surgery, and co-morbid pathology that may directly impact spinal pain.

Following enrollment, each participant completed baseline assessments, including a series of patient reported outcome questionnaires that measured current pain intensity, impact of the patient's LBP on functional status and quality of life, and self-reported medication use. Participants were then allocated to one of two groups: (a) chiropractic care plus UMC or (b) UMC alone. Allocation was carried out via a computer algorithm programmed to balance group assignment; participants and study personnel were unable to influence group assignment.

Participants allocated to the UMC group were allowed to receive any care recommended or prescribed by their individual healthcare providers (not the chiropractic provider) to treat LBP, including self-management advice/education, pharmacological pain management, physical therapy, or pain clinic referral. They were, however, asked to avoid receiving chiropractic care during the active care period of the study (6 weeks) unless directed by their healthcare provider. Participants allocated to the chiropractic care plus UMC group were given access to as many as 12 chiropractic visits during the active care period, in addition to UMC. The number of chiropractic visits was determined individually based on each patient's diagnosis/condition, response to care, and availability. The primary procedures delivered during chiropractic treatment were thrust or non-thrust spinal manipulation in the lower back and adjacent regions. A single chiropractic physician at each site delivered all chiropractic care.

Patient reported outcomes were collected at 2, 4, 6, and 12 weeks following the group allocation. The primary outcome measures were the Numeric Rating Scale (NRS), which asked participants to rate their average level of LBP during the past week via an 11-point scale (where 0=no LBP and 10=worst possible LBP), and the Roland-Morris Disability Questionnaire (RMDQ), a 24-question survey designed to assess self-rated physical disability caused by LBP. Several secondary outcomes measures were also collected to assess perceived improvement, satisfaction, level of bother from symptoms, and medication use, among other measures (as described in Appendix I).

ACT 1 RESULTS

During the period of September 2012 through November 2015, 806 Active Duty military participants were screened, and a total of 750 participants (250 at each site) were enrolled in the study. Each site enrolled 125 participants per group, for a total of 375 participants receiving UMC and 375 participants receiving chiropractic care plus UMC. The study design allowed investigators to analyze the total collected data across all three sites, as well as at each individual site. Across all sites, the average age of participants was 31 years, 32 percent were non-white, and 23 percent were female. At study initiation (baseline), 6 percent of participants reported current use of opioids for back pain and more than half reported use of non-steroidal anti-inflammatory drugs. Fifty-nine percent had never received chiropractic care previously.

During the active period of the study, just over one quarter of the participants assigned to the UMC alone group did not visit a UMC provider during the active period. Those who visited a

UMC provider had a mean number of 2.6 (WRNMMC), 2.3 (NHP), and 2.7 (NMCSD) visits per person. Approximately 29 percent of the participants assigned to the chiropractic care plus UMC group did not visit a UMC provider during the active period. For those who visited a UMC provider, the mean number of visits was 2.6 at WRNMMC, 1.6 at NHP, and 3.5 at NMCSD. For both study groups, a large majority of the participants who did not visit a UMC provider were at NMCSD, which may reflect differences in how patient recruitment was conducted (NMCSD participants were mainly recruited via flyers while participants at NHP and WRNMMC were mainly recruited through primary care clinics). In the chiropractic care plus UMC group, the mean number of chiropractic visits was 4.7 at WRNMMC, 5.4 at NHP, and 2.3 at NMCSD.

At the 6-week primary endpoint, the investigators found statistically significant differences when comparing the two treatment groups. For LBP intensity (measured by the NRS), participants in the chiropractic care plus UMC group indicated a lower mean NRS score than those of participants in the UMC only group, with between-group differences of -0.7 at WRNMMC, -1.2 at NHP, and -1.3 at NMCSD (where lower scores equate to less intense LBP). Findings were similar but with a smaller magnitude of difference at the 12-week time point, indicating that the greater benefit of chiropractic care plus UMC approach continued after the conclusion of chiropractic care delivery. In addition, modest but statistically significant mean differences in self-reported disability (measured by the RMDQ) were seen at both the 6-week and 12-week time points, indicating that participants who received chiropractic care plus UMC reported less physical disability than those in the UMC only group.

Analysis of secondary outcomes supports the greater benefit seen with the addition of chiropractic care, with participants in the chiropractic care plus UMC group reporting significantly lower mean worst LBP intensity within the past 24 hours, lower level of bother from symptoms, better global perceived improvement, and greater satisfaction of care at all sites. As with the primary outcomes, differences between the two groups were modest but statistically significant. No statistically significant differences in self-reported medication use were seen.

Side effects spanned both treatment groups and were generally minor, with the majority described as muscle or joint stiffness due to either the chiropractic treatment or physical therapy (prescribed as part of UMC). No serious adverse events related to the interventions were reported.

NESTED SMOKING CESSATION STUDY

ACT 1 included a nested smoking cessation study, with the goal of measuring the impact of a smoking cessation program delivered by a chiropractor. The investigators sought to test the hypothesis that education and monitoring of smoking habits provided during routine chiropractic care visits for LBP will result in a significant decrease in the average number of cigarettes smoked per week. Participants who self-identified as smokers during the baseline assessment were provided information on the smoking cessation program and given the option to enroll in the nested study. The smoking cessation program was based on the "Clinical Practice Guidelines for Treatment of Tobacco Use and Dependence" [6, 7] and refined for a large randomized controlled trial by Gordon *et al*.[8] The program promoted the use of the "5A's" of tobacco

cessation: (1) **Ask** all patients about tobacco use, (2) **Advise** patients to quit, (3) **Assess** patients' readiness to quit, (4) **Assist** them in completing a personal quit plan with a quit date, and (5) **Arrange** for referrals to tobacco cessation resources and discuss tobacco use at every visit. Thirty-five participants total across the three recruitment sites enrolled in the nested smoking cessation study; one withdrew before completion. Only a small number of the 34 participants answered the question, "How many cigarettes have you had in the past 7 days?" at the 6-week (16 of 34 participants) and 12-week (7 of 34 participants) data collection points. Of those that answered, the quit rate was 0 percent (all were still smoking). Data analysis results with the small sample size were not statistically significant, thus definitive results could not be determined from the nested study. The nested smoking cessation study, which relied on enrollment in ACT 1, is complete and will not be continuing in other studies.

DISCUSSION AND SUMMARY

The RAND Corporation and its partners completed the first of three clinical trials in accordance with section 725 of the NDAA for FY 2010. The ACT 1 trial was a controlled clinical trial that compared the outcomes of chiropractic treatment combined with UMC to UMC alone on pain management in Active Duty military personnel with non-surgical LBP. Aside from a pilot trial conducted by the same investigators, this trial represents the first study designed to evaluate the outcomes of chiropractic care for LBP in Active Duty military personnel. The investigators found that chiropractic care, when added to UMC, resulted in mild to moderate short-term treatment benefits in both LBP intensity and physical disability, demonstrated low risk of harm, and led to higher patient satisfaction and perceived improvement.

The investigators note that the study is not without limitations. Participants were not blinded to their treatment groups, eligibility criteria were broad, a range of interventions was used, and there were differences in visits to UMC providers across the sites. However, these features also demonstrate the potential generalizability of the study results. The study also lacked a clear association between visit numbers and outcomes, suggesting that additional research may be needed to determine appropriate dosing for chiropractic care and establish cost implications in military settings.

The trial has resulted in one publication (Appendix I), which describes the study protocol in detail. A second manuscript outlining trial results is in preparation. The work has been presented at multiple national and international meetings, including the 2016 Association of Chiropractic Colleges Educational Conference and Research Agenda Conference and the 2017 MHS Research Symposium. It was also awarded the Scott Haldeman Award for Outstanding Research by the World Federation of Chiropractic at the DC2017 conference in Washington, D.C.

In summary, the ACT 1 trial results align with results seen in trials with non-military populations and support chiropractic care as a safe and modestly effective treatment to be considered in treatment of LBP.

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2. Muse & Associates, Inc. 2000. *Report on the Department of Defense Chiropractic Health Care Demonstration Project.* Results of independent study conducted by Department of Defense contracted agency. Washington, D.C.

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