



The Honorable Joseph R. Biden, Jr.
President of the Senate
United States Senate
Washington, DC 20510

Dear Mr. President:

The enclosed report is submitted pursuant to section 723 of the Duncan Hunter National Defense Authorization Act for Fiscal Year (FY) 2009 (Public Law 110-417), which requires the Department of Defense (DoD) and the Department of Veterans Affairs (VA) to submit an annual report to Congress on the activities of the Extremity Trauma and Amputation Center of Excellence. This report provides a description and assessment of the activities of the Center during FY 2013. Collaboration between VA and DoD continues to improve rehabilitation techniques, prosthetic and orthotic technology, coordination of care, quality of life, and satisfaction for Service members and Veterans with amputations and extremity trauma. The attached report provides an executive summary and detailed highlights of the outstanding efforts by the Extremity Trauma and Amputation Center of Excellence.

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 Speaker of the House and other congressional committees.

Sincerely,

A handwritten signature in blue ink that reads "Jose D. Riojas".

Jose D. Riojas
Chief of Staff
Department of Veterans Affairs

A handwritten signature in blue ink that reads "Jessica L. Wright".

Jessica L. Wright
Acting Under Secretary of Defense
Personnel and Readiness

Enclosure:
As stated



The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

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The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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cc:
The Honorable James M. Inhofe
Ranking Member



The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Enclosure:
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cc:
The Honorable Adam Smith
Ranking Member



The Honorable Barbara Mikulski
Chairwoman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Madam Chairwoman:

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cc:
The Honorable Richard C. Shelby
Vice Chairman



The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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cc:
The Honorable Nita M. Lowey
Ranking Member



The Honorable Bernard Sanders
Chairman
Committee on Veterans' Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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cc:
The Honorable Richard Burr
Ranking Member



The Honorable Jeff Miller
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, DC 20515

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cc:
The Honorable Michael H. Michaud
Ranking Member

Extremity Trauma and Amputation Center of Excellence Report to Congress



2013

The estimated cost of report or study for the Department of Defense is approximately \$2,510 for the 2013 Fiscal Year. This includes \$0 in expenses and \$2,510 in DoD labor.

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EXECUTIVE SUMMARY

As required by Section 723 of the Duncan Hunter National Defense Authorization Act for Fiscal Year (FY) 2009 (Public Law 110-417), the Department of Defense (DoD) and the Department of Veterans Affairs (VA) are providing a description and assessment of the activities of the Extremity Trauma and Amputation Center of Excellence (EACE) during the 1-year period following the date of the last report. This report includes an assessment of the role of such activities in improving and enhancing the efforts of DoD and VA for the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputation.

During the period October 1, 2012, through September 30, 2013, 68 Service members sustained limb loss, 16 of whom lost multiple limbs; bringing the 11-year total to 1,628 Service members who have sustained a major amputation from conflicts in the Central Command Area of Responsibility. Of the 456 amputees retained on active duty following their amputations, 68 have deployed. There are 246 Service members currently receiving care in one of the three DoD Advanced Rehabilitation Centers (ARC).

Within VA, 43,490 unique Veterans (all conflict eras) with a major amputation received some level of service in the Veterans Health Administration (VHA) during FY 2013; 26,605 of these Veterans received either a prosthetic limb or repair, and/or visited an amputation care clinic. Since 2001, 1,422 Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) era Veterans with amputations have been seen within VA for some level of care or service. Through enhanced collaboration, DoD and VA continue to improve rehabilitation techniques, prosthetic and orthotic technology, coordination of care, quality of life, and health care satisfaction for Service members and Veterans with amputations.

A primary Congressional mandate for the EACE is the development of a comprehensive plan and strategy for DoD-VA in the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputations. The VA Amputation System of Care (ASoC) will continue to receive and provide care for those with traumatic and non-traumatic amputations. The challenge for DoD as traumatic amputations significantly decline with cessation of combat, is how to best maintain the "...continuance of residual knowledge, clinical practices, and extensive research, plus the opportunity to advance the art and science of medical practice and research in the inter-war years, (that) would be of great benefit to care for future generations of the Joint Force" (General Frederick Franks, Jr., U.S. Army (Retired), Member of the Defense Health Board, and a Vietnam Veteran amputee). EACE is committed to studying all successful, existing models to ensure that DoD-VA capabilities for amputation care are maintained for future warfighters and their families.

EACE continues to emerge, as it strives for full operational capability, as an organization with significant gains in staffing and organizational development. EACE now has 18 staff members on board. An Army workforce concept plan was submitted to obtain approval and documentation of workforce requirements to sustain its mission. Work progressed on several strategic clinical education objectives, including the development of a monthly Web-based DoD-VA Virtual Rehabilitation Grand Rounds Program. Additionally, the DoD-VA subject matter expert panel developing a Clinical Practice Guideline (CPG) for Upper Limb Amputation Rehabilitation achieved significant progress toward their established goals. Development of the guideline is on track for completion in FY 2014, and will leverage 11 years of unprecedented experience, expertise, and research into an enhanced standard of care for the 282 upper limb amputees from OEF/OIF/OND. EACE also made significant progress in developing the amputee patient functional requirements for incorporation into the future integrated Health Registries Framework (iHRF).

Extremity trauma and amputation research initiatives within DoD and VA are continued priorities for EACE. During the reporting period, DoD intramural research efforts directed and/or executed by EACE personnel led to 11 new Institutional Review Board approved studies, 18 peer-reviewed publications, and 26 platform and podium presentations at national and international conferences. The newly hired EACE research staff at the ARCs have successfully collaborated with key DoD and VA clinical and research staff to advance amputation and extremity trauma research program efforts during FY 2013.

As part of a growing global outreach mission, EACE continues to assess DoD clinical capacity and provide critical guidance to the Office of the Secretary of Defense regarding medical regulation of Secretarial Designee patients to the ARCs. In support of major combatant commands, EACE provided U.S. Southern Command (SOUTHCOM) with direct support for on-site assessment of amputee care in Colombia in February 2013. EACE staff also continued to monitor progress on the recommendations made to the U.S. European Command (EUCOM) Building Amputee Capability – Georgia (BAC-G) staff in 2012.

INTRODUCTION

As required by section 723 of the Duncan Hunter National Defense Authorization Act for FY 2009 (Public Law 110-417), a description and assessment of the activities of EACE during the 1-year period ending on the date of such report, including an assessment of the role of such activities in improving and enhancing the efforts of DoD and VA for the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputation is provided.

BACKGROUND

The mission of EACE is to serve as the joint DoD and VA lead element focused on the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputations; to implement a comprehensive plan and strategy, to conduct clinically relevant research, foster collaboration and build partnerships across the multidisciplinary international, Federal and academic networks to optimize the quality of life of Service members and Veterans. The EACE Executive Office, located in San Antonio, Texas, serves as the central coordinating body for EACE activities. EACE's Executive Office recommends and supports development of policy for the multidisciplinary network of care detailed below. In addition, EACE synchronizes and promotes collaborative efforts within DoD and VA to enhance the delivery of care and advancement of the science surrounding extremity trauma and amputation.

EACE coordinates and synchronizes efforts within the military health care network across three DoD ARCs: the Military Advanced Training Center at Walter Reed National Military Medical Center in Bethesda, Maryland; the Center for the Intrepid at the San Antonio Military Medical Center in San Antonio, Texas; and the Comprehensive Combat and Complex Casualty Care Program at the Naval Medical Center San Diego, in San Diego, California. EACE and DoD ARCs also coordinate with VA's ASoC consisting of seven Regional Amputation Centers (Bronx, New York; Richmond, Virginia; Tampa, Florida; Minneapolis, Minnesota; Seattle, Washington; Denver, Colorado; and Palo Alto, California); 15 Polytrauma Amputation Network Sites, and 111 Amputation Care Teams across the Nation.

During the period October 1, 2012, through September 30, 2013, 68 Service members sustained limb loss, 16 of whom lost multiple limbs, bringing the 11 year total to 1,628 Service members who have sustained a major amputation in OEF/OIF/OND. Of the 1628, 504 have lost 2 or more limbs, including 5 Service members with loss of all 4 extremities. The vast majority of acute care and initial rehabilitation has occurred within the DoD ARCs, which continue to provide state of the art rehabilitative techniques and advanced prosthetic technologies that facilitate maximum functional outcomes. Of the 1628 amputees, 456 have been voluntarily retained on active duty and 68 have deployed to a combat theater of operations; 246 Service members remain in care at DoD facilities. There are 1,422 OEF/OIF/OND era Veterans with an amputation who have received care in VHA.

DISCUSSION

EACE, through a balanced scorecard methodology, prioritized strategic objectives and aligned resources to our objectives to meet the needs of our population of interest and other key stakeholders. Performance and risk indicators for each strategic objective were developed to better inform decision-makers and measure progress toward desired results. This methodology will focus EACE on key initiatives needed to achieve its vision and improve value to Service members and Veterans, their families, and internal and external stakeholders. Other benefits include a DoD-VA entity with improved efficiency, defined priorities, enhanced interdepartmental communications, and optimized resource utilization.

EACE is focused on continuing to build on experience gained. We are assessing the changing needs of the patient population, as well as looking to sustain the momentum of advances in clinical practice and prosthetic and orthotic technology developed during the past 11 years of conflict. EACE engages key stakeholders in DoD and VA to design collaborative protocols to sustain medical, surgical, and rehabilitation staff competencies, develop new technologies, and improve care leading to maximum functional outcomes and improved quality of life.

EACE is organized into four primary focus areas of value: research, clinical care, clinical informatics and technology, and global outreach.

Research Focus Area of Value: Research focused area staff provide leadership and oversight to identify, prioritize, and conduct research that will ensure the definition and ongoing provision of high-quality amputation and extremity trauma treatment and management strategies.

The EACE Research and Surveillance Division staff work closely with patients and clinicians at the three DoD ARCs, the US Army Medical Research and Materiel Command's (MRMC) Peer Reviewed Orthopedic Research Program at the Congressionally Directed Medical Research Program (CDMRP) and the Advanced Prosthetics Program at the Telemedicine and Advanced Technology Research Center (TATRC), along with the VHA Office of Research and Development (ORD) to stay abreast of clinical questions that can be addressed through well-developed, focused research efforts.

Major accomplishments of the Research Focus Area during FY 2013 are summarized as follows:

The EACE Research and Surveillance Division provides coordination, oversight, and support for approved extremity trauma and amputation research initiatives within the ARCs. During FY 2013, EACE ARC research activities led to 11 new research projects, 18 publications in peer-reviewed journals, and 26 platform and podium presentations at national and international conferences. In addition, there are numerous, ongoing EACE DoD-VA collaborative research efforts which include:

(1) EACE DoD and VA researchers published a series of papers describing clinical efficacy of the BiOM®, a prosthetic ankle device designed to provide artificial muscle power that enables amputees to walk with reduced fatigue and pain, improved stability and balance, and enhanced overall quality of life. Further, EACE, DoD, and VA researchers successfully competed for and received \$1.4M of research funding from MRMC CDMRP to collaboratively pursue this line of research.

(2) The DEKA Arm Take Home Study was funded July 1, 2012 by VA to examine the feasibility, acceptance, and benefits of home use of an advanced upper limb prosthetic device, as well as the logistical support requirements utilized during 3 months of home usage. There are three VA sites and one DoD site participating in the study. At the end of FY 2013, 22 subjects have been screened for potential participation. Twelve subjects have been or are currently enrolled for the in-laboratory portion of the study (nine have completed). Seven subjects have been or are currently enrolled in the 3 month at-home portion of the study (five have completed). Recruitment and enrollment will continue for the next 2 years.

(3) The “Comprehensive High-level Activity Mobility Predictor (CHAMP)” was developed by a VA researcher as a performance-based assessment instrument to quantify high-level mobility in Service members with traumatic lower limb loss. Six papers authored collaboratively by DoD, EACE, and VA researchers were accepted for publication in FY2013 that demonstrate the validity of this tool to discriminate between different levels of lower limb loss and to establish reference ranges for Service members with and without limb loss. This valuable tool is now being used at the ARCs to aid clinicians and patients in tracking the progression of rehabilitation, and in setting realistic goals to reach full functional potential following amputation.

(4) EACE personnel participated in development of the second edition of the VA-DoD Collaboration Guidebook for Healthcare Research, now available online at: <http://www.research.va.gov/va-dod/> This updated guidebook will facilitate continued development of stronger collaborative human subject research relationships between VA and DoD. Such collaboration results in improved research initiatives, as well as pooled financial and human resources, increasing research efficiency, and credibility. Funding for this revised guidebook was provided by VA's ORD.

(5) EACE, DoD, and VA personnel participated as “Chair” and members of the Scientific Steering Committee for Neuromusculoskeletal Rehabilitation, Clinical and Rehabilitative Medicine Research Program, MRMC, to identify and summarize clinically meaningful research gap areas that facilitated DoD and VA research funding decisions. EACE invited representatives from the Amputee Coalition, TATRC, VA representatives, three DoD medical treatment facilities, the Army Medical Department Center and School, and MRMC to work collaboratively to achieve this goal. The team also modified EACE key research initiatives to align with defined gap areas. The following are agreed upon clinical goals which will inform planning for research funding in DoD and VA, now and into the future. These include, but are not limited to:

- a. Safely return patients with amputation to high-level athletic activities;

- b. Return patients to run, jump and agility activities following limb reconstruction;
- c. Optimize gait patterns in patients with amputation;
- d. Decrease pain in patients with amputation;
- e. Provide prosthetic solutions that encourage prosthetic use and improve function for patients with amputation;
- f. Prevent and treat secondary health effects that can develop after primary neuromusculoskeletal injury;
- g. Facilitate optimal reintegration into military or civilian communities; and
- h. Implement standardized health and functional outcomes across DoD-VA.

(6) DoD, EACE, and VA personnel collaborated with the DoD funded "Bridging Advanced Developments for Exceptional Rehabilitation" (BADER) research consortium team to successfully develop and receive \$1.4M in funding from MRMC CDMRP for a study that builds on FY 2012 North Atlantic Treaty Organization recommendations to further develop a functional outcomes assessment toolkit that can be used to standardize outcomes measurement across DoD and VA. Execution efforts for this study, which will collect data across five DoD and VA sites, are underway.

Clinical Care Focus Area of Value: EACE clinical care staff members analyze and disseminate the most current evidence-based practices to DoD-VA clinicians. This staff develops strategies to enhance collaboration and reduce variation in clinical practices between VA and DoD providers and ensure a continuum of care across the two health care systems.

There have been multiple clinical care initiatives promulgated by EACE in FY2013:

(1) EACE promoted state-of-the-art care by executing clinical research and providing science-based evidence to clinicians to support prosthetic prescription and better identify patients who may benefit from the most advanced prostheses. Such devices include the X3® lower extremity and BiOM® prostheses in both DoD and VA. The X3® is a ruggedized, water-resistant version of the X2®, which was the first prosthetic knee to enable above-knee amputees to run forward and backward and ascend stairs and slopes foot over foot. The BiOM® is a powered ankle which may substantially benefit lower limb amputees and potentially aid in community ambulation that might otherwise be impossible.

(2) EACE obtained authorization from the VA-DoD Health Executive Council's Evidence Based Practice Workgroup in FY2012 to develop a DoD-VA Upper Extremity Amputation Rehabilitation CPG. Significant progress has been made in developing the

first clinical pathway/standard of care for this population of patients. DoD and VA have amassed unprecedented experience, expertise, and research in the care of the upper extremity and multi-limb amputee over the past decade of conflict, and subject matter experts from both Departments have been working collaboratively to accomplish this critical task. This CPG will culminate in reduced practice variance, enhanced standard of care, accelerated research translation into clinical practice, and will ultimately lead to improved health, quality of life, and satisfaction for this patient cohort.

(3) Building on existing DoD-VA infrastructure and established training mechanisms, EACE is collaborating with DoD and VHA educational and clinical programs to produce a monthly, combined Virtual Rehabilitation Grand Rounds Program. These seminars provide state-of-the-science programs and continuing medical education for providers across DoD and VA. This significant collaborative clinical training initiative provides a rapid capability to translate research into practice, rather than the slower, traditional route via peer-reviewed publication and subsequent CPG development. The Virtual Rehabilitation Grand Rounds Program will reduce variation in care, meet provider need for continuing medical education, result in travel cost avoidance, increase provider availability for clinical duties, enhance information sharing, foster access to the latest science, and improve the provision of high quality patient care.

(4) EACE has worked to further develop policy and information regarding hand transplant for Service members and Veterans with upper limb amputation. Although not yet considered standard of care, hand transplant research is supported by DoD funding. One OIF Veteran who sustained loss of all four extremities received a bilateral hand transplant at Johns Hopkins Transplant Center in Baltimore in FY 2013. Other Service members who are considering hand transplant are provided an opportunity to seek information from a multidisciplinary panel of DoD and VA providers, counselors, and scientists to assist the amputee and their family in making their decision.

Clinical Informatics and Technology Focus Area of Value: EACE clinical informatics and technology staff serves to develop and manage data and information reported through DoD and VA health care systems to support improved treatment strategies, mitigation of long-term disability, and EACE research efforts. This staff is responsible for maintaining the consistency of data and reports, entering data, generating reports, monitoring utilization of data, and verifying and controlling access limits, as determined by role-based permissions.

EACE demonstrated significant progress in the area of clinical informatics. The legacy amputee database was significantly upgraded to a more robust, stable environment with an increased capacity, additional secure data linkages, and an improved database design and functionality. EACE has simultaneously laid the ground work for a second generation extremity trauma and amputation registry, in concert with the iHRF effort led by the Office of the Assistant Secretary of Defense (Health Affairs) (OASD (HA)). This registry will require extensive development and collaboration to build, and will serve as the sole system of record for tracking Service members from point of injury through various levels of medical and rehabilitative care. EACE is currently developing the

comprehensive functional requirements required to develop necessary technical specifications and pursuing OASD (HA) approval and funding to proceed to the next level of registry development.

EACE established a web presence this year on health.mil and introduced an EACE SharePoint portal to facilitate DoD-VA collaboration and provide a future platform for collaboration with academia and industry. EACE clinical informatics and technology staff were instrumental in the development of the DoD-VA Virtual Rehabilitation Grand Rounds Program by addressing DoD-VA technical system interoperability issues.

Global Outreach Focus Area of Value: The EACE global outreach staff serve to build relationships with applicable national and international entities to maintain clinical readiness, enhance education, develop research partners, and support efforts related to traumatic extremity injuries and amputations. Education and training are crucial components of global outreach and support the implementation of evidenced-based programs.

The EACE Executive Director, along with subject matter experts from the Center for the Intrepid, teamed with SOUTHCOM staff for a site visit to Colombia. The visit objective was to evaluate progress made since previous visits, perform a clinical care evaluation on their most complex amputee patients, and to make additional recommendations for improvements to the Colombian amputation system of care. This was a high-priority engagement for SOUTHCOM and was well received by the senior leadership in the Colombian Ministry of National Defence.

EACE continues outreach assistance to the Republic of Georgia (RoG) and European Command (EUCOM) staff that are organizing and executing the Building Amputation Capability – BAC-G Plan. The RoG Ministry of Defense (MoD) is progressing toward established goals for development of amputee care capability. However, they are missing the core competencies of an interdisciplinary rehabilitation model and most notably, they have no in-country socket and prosthetics fabrication capability for Wounded Warrior care. EACE and EUCOM guided the Georgian MoD with development of a plan committed to interim and long-term goals to address building capability for the full continuum of care for their less complex Wounded Warrior amputees. These plans address facilities, personnel, training and education, equipment goals, and objectives to achieve interdisciplinary rehabilitation and prosthetics capability by the end of calendar year 2015. EACE continues to assess DoD clinical capacity and provide critical guidance to OASD(HA) regarding placement of Secretarial Designee patients in the ARCs.

CONCLUSION

There have been significant EACE accomplishments in FY 2013 with many successful research and outreach efforts, as well as facilitating provision of outstanding clinical care and superior technology. EACE efforts in FY 2014 will remain focused on building staffing and organizational practices for the emerging Center of Excellence. EACE will continue to concentrate on completing the Upper Extremity CPG, completing the first

phase of upgrade to the patient registry, and progressing toward incorporating the EACE registry with the iHRF. EACE places a high priority on conducting studies and other research imperatives and will further establish research portfolios for the embedded ARC researchers. EACE is engaged in planning for care of delayed amputees, expanding boundaries of limb salvage care, and exploring opportunities for collaboration with both the public and private sector. Thankfully, the number of war-related amputations and catastrophic extremity injuries is rapidly decreasing. EACE is working closely with DoD and VA leaders at many levels to help build a comprehensive plan and strategy to maintain appropriate capabilities for future Service members, Veterans, and their families.