



APR 29 2013

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

Dear Mr. Chairman:

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 FY12. 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.

We would be happy to provide you, or your staff, a more detailed brief if desired. Thank you for your interest in the health and well-being of our Service members, Veterans, and their families.

Sincerely,

Handwritten signature of W. Scott Gould in black ink.

W. Scott Gould
Deputy Secretary
Department of Veterans Affairs

Handwritten signature of Jessica L. Wright in black ink.

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

Enclosure:
As stated

cc:
The Honorable Michael H. Michaud
Ranking Member



APR 29 2013

The Honorable C.W. Bill Young
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member



APR 29 2013

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

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member



APR 29 2013

The Honorable Richard J. Durbin
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Thad Cochran
Vice Chairman



APR 29 2013

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

Dear Madam Chairwoman:

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 FY12. 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.

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Deputy Secretary
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Jessica L. Wright
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Enclosure:
As stated

cc:
The Honorable Richard C. Shelby
Vice Chairman



APR 29 2013

The Honorable Kirsten Gillibrand
Chairman
Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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 FY12. 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.

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Enclosure:
As stated

cc:
The Honorable Lindsey Graham
Ranking Member



APR 29 2013

The Honorable Joe Wilson
Chairman
Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Acting Under Secretary of Defense
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Enclosure:
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cc:
The Honorable Susan A. Davis
Ranking Member



APR 29 2013

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

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Deputy Secretary
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Acting Under Secretary of Defense
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Enclosure:
As stated

cc:
The Honorable Richard Burr
Ranking Member

Extremity Trauma and Amputation Center of Excellence Report to Congress



2012

Preparation of this study/report
cost the Department of Defense
approximately \$1,900 in Fiscal Year 2012.

EXECUTIVE SUMMARY

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

During the period October 1, 2011, through September 30, 2012, 199 Service members suffered limb loss, 78 of whom lost multiple limbs, bringing the ten year total to 1,560 Service members who have suffered a major amputation. Outstanding collaboration between DoD and VA continues to improve rehabilitation techniques, prosthetic and orthotic technology, coordination of care, quality of life, and satisfaction for Service members and Veterans with amputations. Of the 320 amputees retained on active service following their amputations, 55 have redeployed. This is a very positive indicator of the high-quality care and rehabilitation services offered to our Wounded Warriors. A recent VA Office of Inspector General (OIG) report on Prosthetic Limb Care in VA facilities, estimated that of the 838 Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn (OEF/OIF/OND) amputees discharged from active service, as of September 30, 2011, nearly 100 percent had transitioned to VA care within five years of separation and the majority considered their life “full.”

Since the last report, key EACE leadership and research positions were filled, funding was obtained through FY 2016, and the concept of operations was approved. Work progressed toward a pilot concept to integrate existing data systems from both DoD and VA into a “federated” registry from which key characteristics of this population can be obtained; in turn, allowing the study of the variations and effectiveness of acute care, rehabilitation techniques, prosthetic technology and services, incidence of complication, mitigation of secondary disabilities, patient outcomes, and quality of life.

EACE promulgated several outstanding clinical care initiatives including improving outcomes for amputees and severely injured Service members with catastrophic lower leg trauma. The development and use of advanced orthotic and prosthetic technology reduced the number of patients seeking delayed amputation. For those with an amputation, they reported improved function, better quality of life, and a significant decrease in pain. EACE sought and received approval from the VA/DoD Health Executive Council’s Evidence-Based Practice Guideline Work Group for development of a Clinical Practice Guideline (CPG) for Upper Limb Amputation Rehabilitation. This guideline will culminate ten years of unprecedented experience, expertise, and research into an enhanced standard of care for the 271 upper limb amputees from OEF/OIF/OND.

EACE provided extensive collaboration, coordination, oversight, and support of on-going extremity trauma and amputation research initiatives within DoD and VA. During the reporting period, these collaborative efforts led to 16 new studies, 29 peer-reviewed

publications, and 22 platform and podium presentations at national and international conferences. In addition, DoD and VA successfully completed optimization studies on the DEKA Arm, a pre-commercial, advanced upper limb prosthetic device with up to 20 powered movements, leading to three years of “take-home” studies for our upper limb amputees. As part of the EACE global outreach mission, international support was provided through involvement in three North Atlantic Treaty Organization (NATO) Research and Technology Organization (RTO) efforts.

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 one 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 injuries and amputation is provided.

BACKGROUND

The mission of EACE is to facilitate the continuous care and research related to traumatic extremity injuries and amputations across the DoD-VA multidisciplinary health care networks. These networks consist of three DoD Advanced Rehabilitation Centers (ARC): the Military Advanced Training Center at the Walter Reed National Military Medical Center in Bethesda, Maryland; the Center for the Intrepid (CFI) 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, California. The Amputation System of Care within VA consists of seven regional amputation centers: Bronx, New York; Richmond, Virginia; Tampa, Florida; Minneapolis, Minnesota; Seattle, Washington; Denver, Colorado; and Palo Alto, California; in addition to 15 Veterans Affairs polytrauma amputation network sites and 111 amputation care teams across the Nation.

The EACE Executive Office, located in San Antonio, Texas, serves as the central coordinating body for EACE activities. Additionally, the EACE Executive Office develops and recommends policy for the multidisciplinary network of care and provides bidirectional sharing of information with DoD and VA Medical Centers (VAMCs) delivering care and conducting research.

During the period October 1, 2011, through September 30, 2012, there were 199 Service members who suffered limb loss, 78 of whom lost multiple limbs, bringing the 10-year total to 1,560 Service members who have suffered a major amputation. Of those, 482 have lost two or more limbs, including five Service members with loss of all four extremities. The vast majority of the acute care and initial rehabilitation has occurred within the DoD ARCs, which continue to provide rehabilitative techniques and advanced prosthetic technologies that facilitate maximum functional outcomes. Of the 1,560 amputees, 320 have been voluntarily retained on active status and 55 have redeployed to a combat Theater of Operations.

Of the 838 OEF/OIF/OND amputees discharged from active service as of September 30, 2011, a VA Office of Inspector General (OIG) report on Prosthetic Limb Care in VA facilities, released March 8, 2012, estimated that nearly 100 percent had transitioned to VA care within five years of separation and the majority considered their life “full.” While those

Veterans with lower limb amputations expressed greater satisfaction than those with upper limb amputation, EACE, in collaboration with DoD and VA, is working to improve care and technology for the upper limb amputees through improved prosthetics technology and development of a clinical practice guideline for upper limb amputations, as outlined in this report.

DISCUSSION

Critical to success of EACE is the rapid attainment of Initial Operating Capability (IOC), which is defined as 50 percent or greater manning at each DoD ARC, in EACE Directorates, and in the Executive Office. EACE made significant gains in attaining IOC. Both the Executive Director and Deputy Director of EACE were appointed, as well as the Chief of Staff and the EACE Director of Research, during the reporting period. The concept of operations for EACE was approved in January 2012. EACE funding was approved in the FY 2012 – FY 2016 Program Objective Memorandum (POM) cycle and requested in the FY 2013 – FY 2017 POM cycle, which facilitates deliberate resource planning and budget execution.

EACE is organized into four primary focus areas of value, which are defined below: research, clinical care, informatics and information management, and global outreach.

Research Focus Area: Provides 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. In January 2012, the EACE Director for Research was appointed and VA is currently recruiting a Deputy Director for Research.

Among the Centers of Excellence, the EACE has a unique mandate under the Duncan Hunter National Defense Authorization Act for FY 2009 to “conduct research to develop scientific information aimed at saving injured extremities, avoiding amputations, and preserving and restoring the function of injured extremities.” The EACE Research and Surveillance Directorate staff works closely with patients and clinicians at the three DoD ARCs, the Peer Reviewed Orthopaedic Research Program at the Congressionally Directed Medical Research Programs, the Advanced Prosthetics Program at the Telemedicine and Advanced Technology Research Center, and the Veterans Health Administration Office of Research and Development to stay abreast of clinical questions that can be addressed through well-developed, focused research efforts.

EACE has taken the lead in establishing an embedded clinician-researcher personnel infrastructure across the three DoD ARCs to execute a multi-site, clinically-relevant, DoD intramural research program. Twenty percent of the embedded clinical researchers have been hired during this reporting period.

Major accomplishments of the Research Focus Area during FY 2012 are summarized as follows:

The EACE Research and Surveillance Directorate provides coordination, oversight, and support for approved extremity trauma and amputation research initiatives within the ARCs. During FY 2012, EACE ARC research activities led to 16 new research projects, 29

publications in peer-reviewed journals, and 22 platform and podium presentations at national and international conferences. In addition, there are numerous, ongoing EACE DoD-VA collaborative research efforts highlighted below:

- (1) CFI and the Providence VAMC: *L. Resnik, M. Gray, M. Borgia. Measurement of community reintegration in a sample of severely wounded Service members. Journal of Rehabilitation Research and Development, 2011: 48(2): 89-102.*
- (2) CFI and the Minneapolis VAMC: *E.H. Sinitski, A. Hansen, J.M. Wilken. Biomechanics of the ankle-foot system during stair ambulation: implications for design of advanced ankle-foot prostheses. Journal of Biomechanics, 2012, 45: 588-594.*
- (3) Collaborative development of a VA-DoD Collaboration Guidebook for Healthcare Research, published online, and summarized in a publication in Military Medicine. <https://cdmrp.org/files/forms/generic/va-dod-guidebook-research-collaboration.pdf>
L. Resnik, G. Reiber, R.K. Evans, P. Steager, K. Barnabe. New guidebook to facilitate VA/DoD collaborations in health care research. Military Medicine, 2011 Oct; 176(10):1085-7
- (4) Tampa and Manhattan VA Medical Centers and CFI: Successful completion of the DEKA Arm Optimization Study. Additionally, this success led to two VA-funded collaborative efforts at the CFI, Tampa, and Manhattan Medical Centers to optimize the DEKA arm and set the stage for a take home study. *VA Study to Optimize the DEKA Arm. PI L. Resnik, CFI Site PI L. Smurr, OT (Completed); VA DEKA Arm Home Study PI L. Resnik, CFI Site PI L. Smurr, OT (Began July 2012) and Upper Limb Kinematics during Functional Activities: Impact of Prosthetic Use. PI. Resnik, CFI Site PI L. Smurr, Gait Lab D. Gates, J. Wilken (Study Ongoing)*
- (5) Collaborative discussions are ongoing between DoD sites and the Salt Lake City VA Medical Center to facilitate a clinical trial of osseointegration, defined as “the formation of a direct interface between an implant and bone, without intervening soft tissue.” The study is projected to begin at the Salt Lake City VA Medical Center in 2013 and potentially could include DoD facilities as early as 2014.
- (6) The EACE research leadership located within CFI is spearheading an effort to establish and publish reliable, valid, and relevant science-based metrics for clinical use within the Computer Assisted Rehabilitation Environment (CAREN) systems world-wide. There are currently 16 facilities worldwide utilizing CAREN for clinical care, with three of these systems located within the EACE ARC sites. To date, CFI has published seven manuscripts related to CAREN treatment, four of which were during FY 2012.
- (7) In support of the EACE global outreach mission, ARC sites have participated in international efforts to meet clinical needs of defense forces world-wide through involvement in three NATO RTO efforts. RTO is the single focus in NATO for defense research and technology activities, with a mission to conduct and promote

cooperative research and information exchange. In FY 2012, EACE participated in three Human Factors Medicine initiatives to support this NATO effort.

Clinical Care Focus Area: The EACE Clinical Care Directorate serves to analyze and disseminate the most current standards of care and evidence-based practices. This Directorate develops strategies to enhance collaboration and standardization of care between VA and DoD providers, enhancing consistency and a seamless continuum of care across the two health care systems. Upon approval of our EACE Army Manpower Concept Plan, EACE and VA will hire the Director and Deputy Director for Clinical Care.

There have been multiple clinical care initiatives promulgated by EACE this FY:

- (1) Provided state of the art care by fitting the Genium, X2, and X3 lower extremity prostheses: The X3 is a ruggedized version of the X2, which was the first prosthetic knee to enable users to run forward and backward and go up stairs and slopes foot over foot. In addition to the three DoD ARC sites, amputation care teams at VA health care facilities have been trained and are fitting the Genium and X2 prostheses. Amputees fitted with these prostheses report a significant decrease in pain and improved quality of life.
- (2) Improved clinical care and patient outcomes through use of the Intrepid Dynamic Exoskeletal Orthosis (IDEO): The IDEO was developed in 2009 at CFI to meet the needs of severely injured Service members who sustained catastrophic foot and ankle injuries resulting in disabling pain and/or weakness, many of whom were considering delayed amputations. The delayed amputation rate, defined as an amputation performed greater than 90 days after injury, has decreased by 50 percent since routinely prescribing this device for limb salvage patients at CFI.
- (3) Completion of the DEKA Arm Optimization Study, a multi-year, multi-site study with 33 unique upper limb amputees providing feedback and information to produce a third-generation arm with sleeker contours, internal battery for some levels, and features not currently commercially available. A take home study, started in July 2012, will look at real life acceptance, impact on quality of life, community integration, and service and support needs.
- (4) Enhanced standardization and clinical quality of care: EACE is enhancing standardization and quality of care by reviewing current CPGs to ensure they are current and relevant and by promoting development of new CPGs to fill “gaps” in care. EACE was recently approved by the DoD-VA Health Executive Council Evidence Based Practice Guidelines Work Group for development of a CPG for Rehabilitation of the Upper Extremity Amputee. DoD and VA have amassed an unprecedented amount of experience, expertise, and research in the care of the upper extremity and multi-limb amputee over the past decade of conflict. Having this CPG will culminate in an enhanced standard of care, accelerated research translation into clinical practice, and ultimately lead to improved health, quality of life, and satisfaction for this population of patients, much the same as the Lower Extremity

Amputee CPG has done for the Service member and Veteran with amputation of their lower limb(s).

Informatics and Information Management Focus Area: The EACE Informatics and Information Management (I/IM) Directorate 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. The Directorate 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. Upon completion and approval of the EACE Army Manpower Concept Plan, EACE will hire the EACE Director for I/IM.

A crucial initiative for the I/IM Directorate is to define and quantify the key demographic, socioeconomic, and co-morbid characteristics of DoD and VA beneficiaries affected by traumatic extremity injury and amputation. The key to achieving this goal is to establish a “federated” registry/repository of patient information. The Vision Center of Excellence is working toward a pilot of this concept which may provide the necessary health information registry data store enterprise capability. A functional working group has been established by EACE to identify crucial data elements, which would integrate data and information from many existing or developing data sources and outcome tools. These existing data systems include the Joint Theater Trauma Registry, Military Orthopaedic Trauma Registry, the VA Amputation System of Care Outcome Repository, and other clinical and non-clinical data sources. Through these linkages, the federated registry will identify individuals, demographics, and practices to enable study of the variations and effectiveness of acute care, rehabilitation care, prosthetic technology and services, incidence of complications, mitigation of secondary disabilities, patient outcomes, and quality of life.

Global Outreach Focus Area: The EACE Global Outreach Directorate serves 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.

A significant effort was made by the EACE Global Outreach Directorate during a site visit led by the EACE Executive Director, attending a U.S. European Command (EUCOM) sponsored conference in Tbilisi, Republic of Georgia (RoG). The visit objective was to develop a plan, including a timeline and milestones, to establish an amputee care system for the RoG. The EUCOM is publishing a guideline for this effort, based on significant input from EACE. The Georgian Ministry of Defense has committed to providing pre-prosthetic care and establishing a unilateral below-knee amputee care capability. In the interim, EACE continues to assess DoD clinical capacity and provide critical guidance to the Office of the Assistant Secretary of Defense for Health Affairs regarding placement of secretarial designee patients in the ARCs.

CONCLUSION

Although the number of Service members and Veterans with amputations and catastrophic extremity injury continues to increase, the collaborative efforts of DoD, VA, and EACE to

ensure the expertise, experience, and research findings are translated into the pinnacle of clinical care, rehabilitation, and technology available to this population have been phenomenal. Service members with catastrophic extremity injury and amputation who were retained on active service, deployed to the Central Command Area of Responsibility with their units, or expressed “fullness” of life after separation, demonstrate not only the character and drive of these young men and women, but also the stellar work within DoD, VA, and EACE to ensure every effort is made to improve the health, quality of life, and satisfaction for these Service members and Veterans.

There has been a vast amount of work accomplished in the past year with the many successful research and outreach efforts, as well as provision of outstanding clinical care and superior technology. EACE will continue to focus on providing unsurpassed care and technology in the coming year, as well as developing the Upper Extremity CPG, the registry, conducting studies and other research imperatives, filling the embedded researcher positions in the ARCs, and exploring opportunities for collaboration with both the public and private sector.