INTRODUCTION

The Congressionally Directed Medical Research Programs (CDMRP) represents a unique partnership among the U.S. Congress, the military, and the public to fund innovative and impactful medical research in targeted program areas. In 2015, an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine was assembled to evaluate the CDMRP’s two-tier review process and its coordination of research priorities with the National Institutes of Health (NIH) and the Department of Veterans Affairs (VA). As part of their final report, the committee recommended that each CDMRP program “… develop a strategic plan that identifies and evaluates research foci, benchmarks for success, and investment opportunities for 3–5 years into the future,” and that these strategic plans “should specify the mission of the program, coordination activities with other organizations, research priorities, how those priorities will be addressed by future award mechanisms, how research outcomes will be tracked, and how outcomes will inform future research initiatives.”

In response to these recommendations, this document presents the current strategy for the CDMRP’s Orthotics and Prosthetics Outcomes Research Program (OPORP). The OPORP Strategic Plan identifies the high-impact research goals most important to its stakeholders while providing a framework that is adaptable to changes in the medical research environment to address those goals. This plan has been formulated to provide greater clarity of the program’s goals over time to the public and other stakeholders. Funding for the OPORP is Congressionally appropriated on an annual basis; therefore, there is no guarantee of future funding. The OPORP Strategic Plan will be reviewed during the program’s annual Vision Setting meeting and updated as necessary.

OPORP BACKGROUND AND OVERVIEW

Between 2004 and 2014, more than 1,500 Service members suffered a major amputation in Service to their country. Loss of limb or limb functionality is one of the most debilitating traumatic injuries suffered by U.S. military personnel. Recent advancements in commercially available orthotics and prosthetics have dramatically improved device capability; however, there remains an urgent need for evaluation of devices and treatments to identify those that provide the most improvement in user functionality and quality of life for our Service members.

The OPORP was established by Congress in 2014 to support research of exceptional scientific merit with the potential to make a significant impact on improving the health and well-being of Service members, Veterans, and other individuals living with limb deficit. It supports research to evaluate the comparative effectiveness and functional outcomes associated with prosthetic and orthotic clinical interventions for the purpose of ultimately advancing implementation of the most effective prescriptions for prosthetic and orthotic devices, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers.

VISION: The highest possible quality of life for our injured warfighters through the advancement of knowledge in orthotics and prosthetics related research

MISSION: Advance orthotic and prosthetic research to optimize evidence-based care and clinical outcomes for military-related neuromusculoskeletal injury
**FUNDING HISTORY**
Since its inception in fiscal year 2014 (FY2014), the OPORP has received Congressional appropriations of $10 million (M) each year, for a total of $40M, to facilitate research within the scope of its program framework. In the years since FY14, 306 award applications have been submitted; 32 awards were funded during the FY14-FY16 time period. Six awards are currently under negotiations to fund projects submitted in FY17.

**RESEARCH PORTFOLIO AND RESEARCH ACCOMPLISHMENTS**
Between FY14 and FY17, the OPORP funded applied research; basic/discovery research; behavioral/psychosocial research; clinical trials; epidemiology/public health research; novel outcome development; quality of life studies; and translational research. Half of this funding was invested in clinical trials, and one-fifth was invested in translational research. The OPORP’s current investments are summarized in Figure 1.

**RESEARCH AND FUNDING ENVIRONMENT**

**STATE OF THE SCIENCE**
The OPORP monitors transformational efforts in orthotic and prosthetic research and development, as well as evolving technologies that could alter the landscape of patient outcomes and cause the OPORP to reconsider and adjust its strategic direction, goals, and priorities. While there have been great advances in the technology of orthotics and prosthetics, outcomes research is still needed to inform users, care providers, and policy makers about the best options with regard to quality of life, ability to carry out daily activities, work productivity, and return to duty.

**TRANSFORMATIONAL DATA AND RESEARCH**
Data to support research and studies with the potential to make significant progress toward understanding the comparative effectiveness of various orthotic and prosthetic interventions are important. The availability of new data or significant findings from other groundbreaking studies could impact the direction of the OPORP and will be reviewed regularly. Discussion of how these findings would impact the OPORP’s direction will be included in the annual Vision Setting meeting. Organizations and programs that support highly relevant areas to the OPORP are highlighted below. While these are not the only relevant areas to the program, understanding the focus and success of these related programs and efforts helps the OPORP to collaborate successfully within its field of scientific endeavor, leverage the results achieved by others, utilize its own funds for maximum impact, and effectively engage important stakeholders in furthering the OPORP’s mission. Attending annual meetings or symposia of some of these organizations, communicating with their leaders or members, and inviting them to participate on the OPORP Programmatic Panel are among the ways these groups will be engaged.

**Highly Relevant Organizations and Programs to the OPORP**
- American Academy of Orthotists and Prosthetists
- Defense Advanced Research Projects Agency
  - Revolutionizing Prosthetics Program
  - Hand Proprioception and Touch Interfaces
  - Electrical Prescriptions
Orthotics and Prosthetics Outcomes Research Program

• Department of Defense (DoD)-Related Research Programs
  – Clinical and Rehabilitative Medicine Research Program (CRMRP)
  – Peer Reviewed Orthopedic Research Program
  – Peer Reviewed Medical Research Program (PRMRP)
• Major Extremity Trauma Research Consortium
• National Science Foundation
• NIH
• Patient-Centered Outcomes Research Institute
• Rusk Rehabilitation at NYU Langone Health
• VA

TECHNOLOGY
Today’s technology environment is dynamic, with new developments created and made available at an ever-faster rate. The OPORP continually monitors technology advances to be able to align its research portfolio and priorities with the ever-advancing state of the science. Technology advances that affect patient outcomes to improve the lives of Service members and Veterans recovering from traumatic neuromusculoskeletal injury, as well as their families, their caregivers, and/or the general public, include: (1) 3D printing; (2) advanced (powered) prosthetics; (3) battery life improvements; (4) Bluetooth (microprocessors); (5) camera-less gait analysis technology; (6) exoskeleton systems; (7) autonomous control and proprioception implants and systems; (8) material advances/advances to impact device weight; (9) mind machine interface advances (10) novel socket systems; (11) outcome measure improvements; (12) osseo-integration techniques; (13) the SYMPHONIE aqua system; (14) surgical advances; and (15) wearable sensors.

In continually scanning the technology landscape, the OPORP seeks to understand direct advances in the field of orthotics and prosthetics, as well as other science/technology developments that could be applied in orthotics and prosthetics outcomes research. While other organizations fund research on orthotics and prosthetics, the OPORP is unique in its emphasis on outcomes research. Research of interest to the OPORP that will be monitored is typically funded by the NIH through different institutes such as the National Institute on Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Biomedical Imaging and Bioengineering, as well as the Small Business Innovation Research programs through both the NIH and DoD; the other DoD programs listed above, such as the CRMRP and PRMRP; and other organizations and foundations such as the VA.

STRATEGIC DIRECTION
The OPORP endeavors to improve clinical decision-making and, ultimately, clinical outcomes for injured Warfighters with military-related neuromusculoskeletal injury. The program covers a broad set of clinical research questions concerning comparative effectiveness and outcomes related to a wide range of orthotic and prosthetic devices and treatments. As great technological advances continue in the fields of orthotics and prosthetics, the OPORP will consider expanding its focus to include additional scientific priorities in addition to those outlined above. The inclusion of new priorities to consider in terms of outcomes and focus areas will be considered based upon the results of research conducted by the program in the near term and the progress made by others. If significant breakthroughs happen in particular areas, the program will consider how to adjust its focus to advance research in these areas as needed. The OPORP’s strategic direction will take into account work and progress achieved through other program support, annual levels of funding, and Congressional intent and priorities.

STRATEGIC GOALS
The OPORP has identified three overarching strategic goals to guide its efforts over the next 3-5 years. Both individually and collectively, these goals are focused on enhancing outcomes for Service members and Veterans affected by limb salvage or limb amputation, including optimization of both function and performance, as well as community integration.

Optimize patient-specific technology prescription for the Warfighter
This goal focuses on identifying optimal (1) devices and device characteristics, (2) human interface with the devices, and (3) intuitive control systems, all grounded in an understanding of the requirements of patient-specific needs and the capabilities and limitation of available devices.
Optimize patient-specific rehabilitation regimens for the Warfighter
This goal addresses the cause and effect of an orthotic or prosthetic device on the optimal type, timing, and dosing (duration, frequency, intensity) of rehabilitation for each individual, again in the context of each person’s unique requirements and preferences. The goal also includes efforts to understand the impact of provider competencies and patient training on the effectiveness of the rehabilitation regimen, as well as to identify the best approaches to mitigate secondary health deficits.

Support standardized assessment of patient outcomes related to prosthetics and orthotics
Through this third goal, the OPORP seeks to validate function and performance, community integration, and user satisfaction outcomes associated with various device properties and functional abilities. An important objective of the OPORP is to enhance understanding of the outcomes that matter most for individuals living with orthotic and prosthetic devices.

NEAR-TERM PRIORITIES
In the near term, we seek to improve understanding of the requirements and needs of orthotics and prosthetics users. Special emphasis will be placed on standardized evaluation of the effect of orthotic and/or prosthetic device use on the length, duration, and frequency of rehabilitation and associated outcomes. In addition, we are interested in research on the device form, such as available clinical options for suspension or attachment of the device. We also plan to support research on device fit, such as identification of criteria for optimal fit and evaluation of available clinical options for stump-socket interface. Finally, we will emphasize research on device function, such as evaluating available options for control and proprioception and optimizing the battery life of the device.

MEDIUM- TO LONG-TERM PRIORITIES
In the medium or long term, the OPORP will continue pursuing a broad set of clinical research questions concerning comparative effectiveness and outcomes related to a wide range of orthotic and prosthetic devices and treatments. The OPORP expects its goals and focus areas to evolve according to the findings of its funded research projects, as well as other advances in the field. Its focus will expand to include additional scientific priorities in addition to those outlined above. The inclusion of new priorities will be considered in terms of aspects of outcome evaluation, types of human research, and award mechanisms, based upon the results of research conducted by the program in the near term and the progress made by others. If significant breakthroughs happen in particular areas, the program will consider how to adjust its focus to build on the breakthrough or complement the research advances in these areas as needed. Potential long-term goals include research that will significantly influence clinical practice and inform policy decisions, but will depend on available future funding and the progress made in the field as a whole.

NEAR-TERM FOCUS AREAS
The following three focus areas act as an indicator to the research community of the types of applications that may be of special interest to the FY18 OPORP. Through these focus areas, the OPORP endeavors to further understand patient-specific requirements and the applicability and generalizability of available clinical options to address these requirements.

Orthotic or Prosthetic Device Form
• Understand patient outcomes through analysis and characterization of variables related to the form of currently available clinical options, such as device size, shape, material, and/or configurations.

Orthotic or Prosthetic Device Fit
• Understand patient outcomes related to human-device interface and component connection through analysis of variables in currently available clinical options that facilitate fit-related metrics such as comfort and/or usability.

Orthotic or Prosthetic Device Function
• Understand patient outcomes through the analysis of variables related to currently available device function, such as device control, sensors, and passive or active response, with respect to daily living and other real-world activities.

INVESTMENT STRATEGY
NEAR-TERM MECHANISMS AND STRATEGY
The FY18 OPORP is soliciting research to achieve its strategic goals by providing funding to clinical research and clinical trials focused on patient outcomes. Two funding levels are being offered to fund either pilot research/clinical trials or more mature clinical projects. The FY18 OPORP Clinical Research and Clinical Trial Award mechanisms intend to support research that evaluates orthotic and/or prosthetic devices using patient-centric outcomes that are relevant to Service members and Veterans with limb loss and/or limb impairment, as well as their family members, their caregivers, and/or the general public. They are focused on outcomes-based best practices through analysis of the prosthetic and/or orthotic device options currently available, not on development of a new technology or improvement of an existing technology. The intent of these award mechanisms is to support studies that generate clinically useful evidence that will guide clinical practice and improve patient outcomes.
FUTURE AWARD MECHANISMS
As it has been historically, the OPORP will remain open to a wide range of award mechanisms to support both its strategic goals and its evolving interest in funding meritorious projects to support evidence-based care and clinical outcomes research. These award mechanisms will be considered and evaluated as part of the yearly Vision Setting discussions.

MEASURING PROGRESS

NEAR TERM
The OPORP will measure its near-term success based on the specific contributions of its funded research to the scientific community and the advancement of orthotic and prosthetic outcomes research, such as the following:
• Number of technical reports and presentations related to the OPORP-funded research
• Number of high-quality research applications submitted to OPORP
• Number of new investigators or experienced investigators submitting first-time OPORP research applications and being funded

LONG TERM
Over the long term, success will be measured based on the near-term measures indicated above, as well as the following:
• Percentage of completed OPORP-funded projects
• Number of publications in high-impact, peer-reviewed journals reporting on OPORP-funded research
• Frequency of citations of publications from OPORP-funded research
• Grantees with follow-up funding based on findings from OPORP-funded research
• Utilization of OPORP-funded research outcomes in clinical practice guidelines

REFERENCES