



Orthotics and Prosthetics Outcomes Research Program

Strategic Plan

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. Programs managed by the CDMRP have formalized strategic plans that identify: program-specific research priorities; how to best address these urgencies; short- and long-term goals; investment strategies; and ways to identify and evaluate program successes with respect to the priorities.

The Orthotics and Prosthetics Outcomes Research Program (OPORP) Strategic Plan identifies the high-impact research goals most important to the program and its stakeholders while providing a framework that is adaptable to changes in the medical research and clinical care environments to address those goals. This plan has been formulated to provide greater clarity of the program's goals over time. Congress appropriates funding for the OPORP 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

"The [Senate Appropriations] Committee believes that continued research on orthotics and prosthetics outcomes can further improve care for servicemembers with limb loss and limb impairment and support evidence-based practice by allowing doctors to match servicemembers and veterans with the orthotic or prosthetic that best works for them," Senate Report 113-85, Department of Defense Appropriations Bill, 2014.

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. Between 2001 and 2020, more than 1,700 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 and, as such, has been a primary focus of the OPORP from 2014–2022. Recent increases to the OPORP appropriation (**Figure 1**) have allowed the program to expand its potential impact by supporting research in areas beyond trauma and injury (including, but not limited to, vascular disease, stroke, diabetes, neuropathy, and infection) that have resulted in limb loss or limb impairment that benefits from the use of prosthetic or orthotic devices. Some key data points driving this expansion include the following:

- Of the nearly 2 million people who are living with limb loss in the United States, the leading cause of amputation is attributed to vascular diseases (54%), followed by trauma (45%) and cancer (~1%).² Within the VA health care system alone, the majority of Veterans with amputations have lost limbs due to vascular disease progression.³





- Stroke is currently the leading cause of serious long-term disability in the United States, with 795,000 people experiencing a stroke annually, costing the health care system a total of \$34 billion.⁴ VA facilities see approximately 6,000 people per year, with an additional 60,000 outpatient visits relating to stroke. Individuals who experience a stroke have long-term health effects that can include impacts to coordination and gait, as well as weakness and paralysis of muscles.⁵ Use of orthotics such as ankle-foot orthotics can help stroke patients compensate for muscle weakness and improve overall mobility.
- Up to 55% of persons with diabetes who have a lower extremity amputation will require amputation of the second leg within 2–3 years.⁶ Improving prosthetics and orthotic outcomes in this population may reduce this number.
- Neuropathy, or peripheral nerve pain, can result from a multitude of physical injuries and diseases including but not limited to, diabetes, trauma, autoimmune disorders, infections, vascular disorders, and alcoholism. Pain, both acute and chronic, affects most aspects of quality of life, including physical and emotional functioning. Depending on the severity of pain, braces and orthotic devices may be worn to provide support to the impacted limb and keep the affected nerves in proper alignment.⁷
- Complications such as deep, soft tissue infections and osteomyelitis are commonly seen in combat-related extremity trauma. Studies have found that patients who are diagnosed with these infections are more likely to undergo late amputation after limb salvage attempts.⁸ Improving orthotic outcomes for persons with limb salvage or limb impairment may reduce the impact of these and other infections and may reduce the limb salvage to limb loss conversion rate.

Regardless of the underlying condition that resulted in the limb loss or limb impairment, 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, Veterans, and all persons living with limb loss or limb impairment. The OPORP 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: To attain the highest possible quality of life for individuals with limb loss and limb impairment.

MISSION: Advance orthotic and prosthetic research to optimize evidence-based care and clinical outcomes for Service Members, Veterans, and persons with limb loss and limb impairment.

FUNDING HISTORY AND RESEARCH PORTFOLIO

From its inception in fiscal year 2014 (FY14) through FY23, the OPORP has received \$125 million (M) in congressional appropriations (**Figure 1**) to facilitate research within the scope of its program framework. In the years since FY14, 549 award applications have been submitted, and 80 awards have been funded. An additional 11-13 awards are anticipated for FY22. The OPORP's current investments are summarized in **Figure 2**.

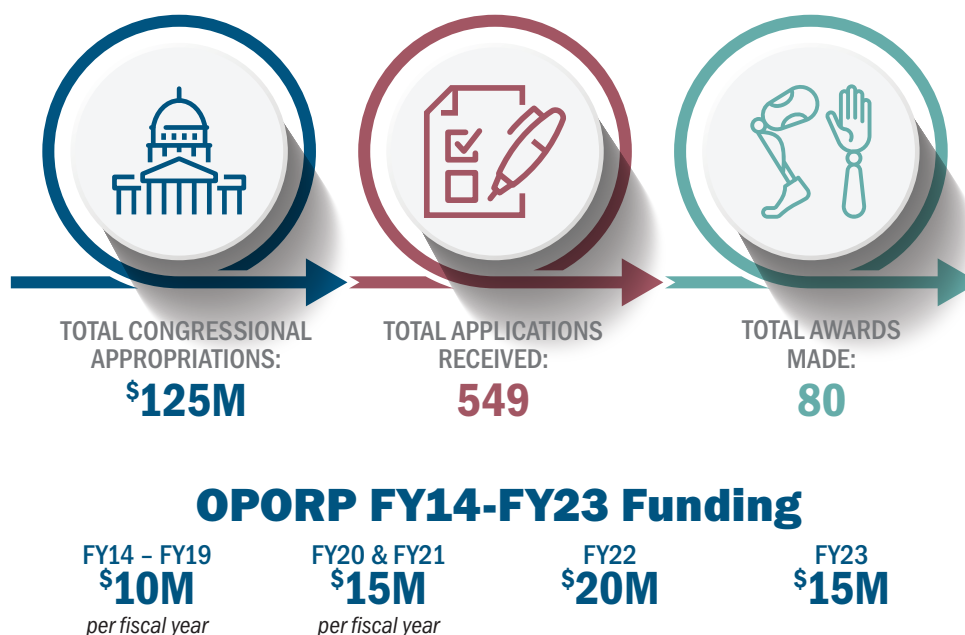


Figure 1. OPORP Investments and Congressional Appropriations.

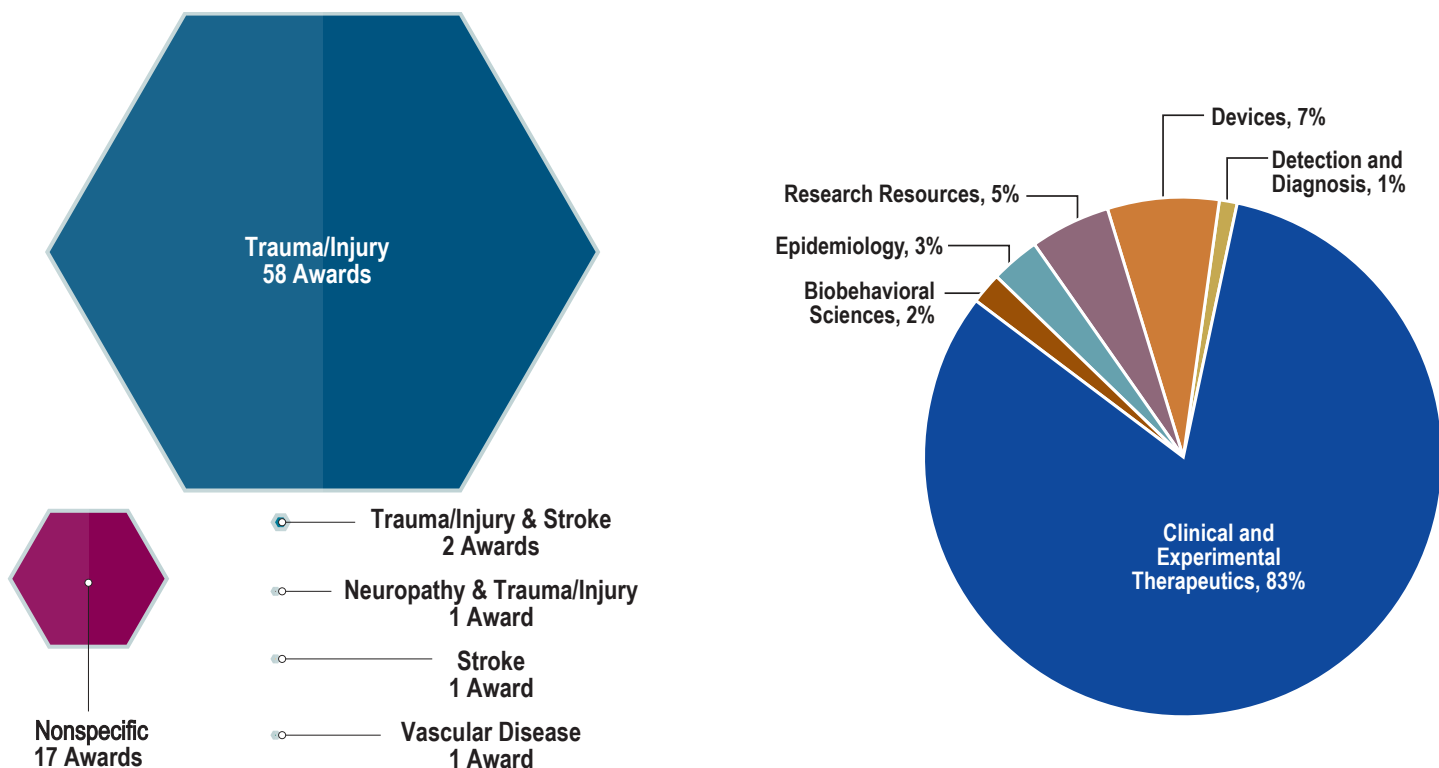


Figure 2. OPORP awards by research (left, FY14–FY21) and topic areas (right, FY14–FY20). A significant portion of the OPORP research portfolio addresses trauma/injury populations. The OPORP anticipates increasing future investments in non-injury topics to maximize impact for other limb loss and limb impairment populations in the near and long term.

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/work.



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
- American Orthotic and Prosthetic Association
- Defense Advanced Research Projects Agency
- Department of Defense (DOD)-Related Research Programs
 - Military Operational Medicine Research Program
 - Peer Reviewed Orthopaedic Research Program
 - Peer Reviewed Medical Research Program
- National Science Foundation
- NIH
- Patient-Centered Outcomes Research Institute
- VA

PATIENT-CENTERED APPROACH

Outcomes research has many implications. Research outcomes of the OPORP have the potential to impact device refinements, prescription practices, user comfort and adaptability, clinical practice standards, and return-to-work/duty rates, among other impacts. The OPORP takes a patient-centered approach to identifying and addressing outcomes that are most relevant to the user, including fall risk and mobility, and will prioritize research focused on improving these outcomes. In order to ensure impacts to patients and patient care remain paramount in OPORP-funded research, applications submitted to the OPORP will be encouraged or required to incorporate at least one limb loss or limb impaired patient/consumer as a consultant or member of the research team to contribute to the development of the research question, project design, oversight, evaluation, and/or other significant aspects of the proposed project. The OPORP will also fund research that provides the clinical evidence to support clinical care decisions that are personalized based on K-level goals (K-levels are a rating system used by Medicare to indicate an individual's functional ability or potential), risk of secondary health effects, limb health, compliance and motivation, risk of limb salvage to limb loss conversion, and a wholistic care approach. Efforts in related topic areas managed by other government and non-government organizations will be leveraged to maximize impact and return on investment in these areas.

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 advancing state of the science. Technology advances that affect patient outcomes for Service Members, Veterans, and persons with limb loss or limb impairment, as well as their families and caregivers, 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) osseointegration techniques; (13) surgical advances; and (14) wearable sensors.

In continually assessing 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 development, validation, and refinement, the OPORP is unique in its emphasis on outcomes research. Research of interest that will be monitored is typically funded by the VA, 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); the National Institute on Disability, Independent Living, and Rehabilitation Research; Small Business Innovation Research programs through both the NIH and DOD; the other DOD programs listed above; and other related organizations and foundations.



STRATEGIC DIRECTION

The OPORP endeavors to improve clinical decision-making and, ultimately, clinical outcomes for all persons with limb loss and limb impairment. 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 technology advances in the fields of orthotics and prosthetics, the OPORP will consider expanding its focus, while staying aligned to congressional direction and language, 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 on the results of research conducted by the program in the near term and the progress made by others. The OPORP's strategic direction will consider work and progress achieved through other program support, annual levels of funding, and congressional intent and priorities.

STRATEGIC GOALS

Within the next 5 years, the OPORP plans to expand its potential impact to the limb loss and limb impairment communities. The OPORP will continue supporting trauma and injury research and will strengthen its non-injury research portfolio including, but not limited to, vascular disease, stroke, diabetes, neuropathy, and infection topics. The focus of all research that will be funded by the OPORP will be on improving outcomes for orthotic and prosthetic device users, particularly for those impacted by limb loss or limb impairment. Of note, the congressional direction for the OPORP does not allow pediatric research. The congressional language attributed to any given years' appropriation will be referenced for any additional requirements related to broadening the current scope.

The OPORP has identified three overarching strategic goals to guide its efforts over the next 5 years. These strategic goals were developed in 2018 and continue to represent the overall goals of the OPORP. Both individually and collectively, these goals are focused on enhancing outcomes for Service Members, Veterans, and all persons affected by limb loss or limb impairment, including optimization of function, comfort, and performance.

Optimize patient-specific technology prescription: 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: 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

OPORP priorities are based on coordination and discussion with other program offices and an assessment of complementary funding investments. The OPORP identifies the funding, knowledge, and capability gaps in order to maximize impact of the program. In the near term, the OPORP seeks to improve understanding of the requirements and needs of orthotics and prosthetics users and, relatedly, their care providers in prescribing the best device and rehabilitation for each individual user. Special emphasis will be placed on improving whole-person outcomes, standardized evaluations, and development of assessment tools to aid in clinical decision-making and device prescription.

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. Additional priorities will be placed on growing the research field by encouraging new researchers and established researchers from other relevant areas to help the OPORP meet its mission. 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 on the results of research conducted by the program in the near term and the progress made by others. Potential long-term goals include research that will significantly influence clinical practice and inform policy decisions and will depend on available future funding and the progress made in the field as a whole.



INVESTMENT STRATEGY

NEAR-TERM MECHANISMS AND STRATEGY

The OPORP solicits research to achieve its strategic goals by providing funding for clinical research and clinical trials focused on improving outcomes for Service Members, Veterans, and persons with limb loss and/or limb impairment. The exact mechanism and focus areas to be offered any given fiscal year will depend on congressional direction/language, program priorities and portfolio balance, current research and the funding landscape, and the current state of science, technology, and clinical care. The OPORP will prioritize clinical research and research partnership mechanisms and is also interested in supporting new investigators, early ideas, implementation science, and health disparity research in the near future.

As required by the law, all OPORP-funded research must be focused on outcomes-based best practices through analysis of the prosthetic and/or orthotic device options currently available, not on development of a new device or improvement of an existing device. 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

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 and clinical care communities as well as the advancement of orthotic and prosthetic outcomes research, such as the following:

- Number of presentations related to the OPORP-funded research
- Number of high-quality research applications submitted to the OPORP
- Number of new investigators or new applicants submitting first-time OPORP research applications
- Portfolio diversity and synergy with other research funders

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 with actionable research outcomes
- 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-on funding based on findings from OPORP-funded research
- Utilization of OPORP-funded research outcomes in clinical practice guidelines



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