Outcomes Research and Evidence Based Practice Help P&O Providers and Their Clients

Evidence based practice (EBP) seeks to improve patient care through the systematic collection, analysis and publication of medical data. Clinicians recognize that measurable, objective data about treatment outcomes inform clinical practice and substantiate prescribed interventions. Medical specialties and institutions propose treatment that is consonant with evidence based medical and surgical guidelines. The largest of these institutions are the Department of Veterans Affairs and the Department of Defense (VA/DoD), which jointly have formulated the VA/DoD Clinical Practice Guidelines (CPG) to improve and standardize the quality of care and management of many conditions, including stroke rehabilitation, traumatic brain injury (TBI), lower limb amputation, post traumatic stress disorder (PTSD), chronic pain and fatigue syndrome, diabetes, acute postoperative pain, major depressive disorder, and many others. Practitioners in most institutions use patient outcomes to validate the most effective treatments, reduce costs and improve insurance reimbursement.

The Center for Rehabilitation Outcomes Research (CROR) is collaborating with Northwestern University Rehabilitation Engineering Research Center (NURERC) under NIDRR grant (H133E080009) to conduct a study that measures the quality of P&O services using process and outcome information. Allen Heinemann, Ph.D., et al., describe this project in “Enhancing the Quality of P&O Patient Care through Outcomes Measurement.” During the next four years, CROR will recruit five P&O facilities that are accredited by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC). CROR researchers will develop a database of process and outcome indicators that are useful in guiding clinical practice improvement activities; deliver and evaluate the curriculum on use of quality indicators to improve clinical practice and outcomes; implement quality improvement activities based on performance monitoring; revise quality improvement curriculum based on facility feedback; and evaluate facility performance with accreditation surveys, Orthotics and Prosthetics Users’ Survey (OPUS) data, and facility feedback.

To promote evidence based practice in P&O, the American Orthotic and Prosthetic Association (AOPA) has initiated an Evidence Note that is designed to help P&O professionals justify their treatment decisions and improve the quality of P&O care. Stefania Fatone, Ph.D., discusses the principles that underlie Evidence Notes in “Facilitating Outcomes Research in O&P.” Ideally, prior to prescribing a device, P&O personnel will be able to refer to Evidence Notes for concise and thorough synopses of various conditions. The Evidence Note begins with “Key Points” that highlight principal facets of a condition. Comprehensive summaries address a specific treatment with respect to its epidemiology, economic implications, relevant research and substantiating references. Evidence Notes are designed to offer a clearly structured and standardized rationale for the prescription of P&O devices and modalities. In turn, these standardizations of P&O management modalities may improve insurance reimbursements, thus assisting both practitioners and their clientele.

From VA/DoD to solo practices, prosthetists and orthotists are working systematically to measure outcomes, establish standards of treatment, comply with accreditation, and improve the quality of care for P&O clients. The collaborative work conducted by CROR and NURERC will benefit prosthetists, orthotists and their clients by monitoring and guiding clinical practice with instruments that accurately measure outcomes. Similarly, Evidence Notes will help P&O professionals achieve evidence based standards for treatment decisions, quality of care, and compliance with standards. These efforts also may generate increased client satisfaction with service and devices and better insurance reimbursements.

R. J. Garrick, Ph.D.
Capabilities, Editor
Enhancing the quality of patient care is an important issue for practitioners in the field of prosthetics and orthotics (P&O). To receive and maintain accreditation, the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) has established Performance Management and Improvement Standards that require P&O facilities to collect and report patient satisfaction feedback. Notably, only accredited P&O facilities are eligible for reimbursement from the Centers for Medicare and Medicaid Services. Collecting and reporting these data are essential to monitor and improve quality of P&O care; however, burdens of cost and time may hinder implementation. As one of the projects funded by the National Institute on Disability and Rehabilitation Research (NIDRR) at the Northwestern University Rehabilitation Engineering Research Center (NURERC) for Prosthetics and Orthotics (P&O), Allen Heinemann, Ph.D., and Linda Ehrlich-Jones, Ph.D., RN, assisted by project manager, Dustin Williams, M.S., of the Center for Rehabilitation Outcomes Research (CROR) at the Rehabilitation Institute of Chicago (RIC), are conducting the Outcomes Measurement Project. In addition to collaborating with NURERC, the CROR project also coordinates with ABC, the American Orthotics and Prosthetics Association (AOPA), the Northwestern University Prosthetics and Orthotics Center (NUPOC), and Focus on Therapeutic Outcomes, Inc. (FOTO) (Knoxville, TN). In support of ABC accreditation standards, the goals of this consultation project are to improve the quality of P&O patient care through the use of standard outcome measures; and to provide on-line, quality improvement education for P&O providers.

The current project builds on the Orthotics and Prosthetics Users’ Survey (OPUS)², developed by Dr. Heinemann and his associates during work that was conducted under NURERC’s prior NIDRR grant. OPUS is a self-report instrument that assesses P&O patients’ functional status, quality of life, and satisfaction with P&O services and devices. Five, Midwestern P&O service providers have been recruited to participate in the Outcomes Measurement Project. These P&O providers will use the OPUS for all first-time and returning patients who require a new prosthesis or orthosis. Patients will complete the OPUS components at their first and last clinic appointments and at a 3-month follow-up. At the time of discharge and at the 3-month follow-up, patients also complete the satisfaction with service and device module. These tools will enable clinicians to standardize data collection and evaluate outcomes for individual patients and programs.

FOTO will provide the outcomes monitoring, data collection, reporting, and education programs accessible to practitioners. Jointly, NUPOC and CROR will develop an online, educational program to help prosthetists and orthotists improve their quality of patient care and comply with ABC accreditation standards. FOTO will receive digital transmissions of OPUS data collected from patients. FOTO will enter these data to a secure database where participating service providers can access the outcomes.

Based on the outcomes assembled from qualitative patient reports, the CROR team will consult with the P&O practitioners to review their clinical performance and to help them develop quality improvement strategies that integrate ABC quality standards into their daily practice. Also, the online educational module will offer effective ways that P&O practitioners can integrate outcome information, promote quality of care improvement, and fulfill ABC accreditation.

John W. Michael, M.Ed., CPO/L, FAAOP, and President of CPO Services, Inc. (Portage, IN), notes that this project will help P&O providers apply outcome information and improve clinical practices. Mr. Michael observed, “To the best of my knowledge, OPUS is unique because it is the only validated outcome measurement directed at both P&O patients and providers that looks at functional outcomes, patient/customer satisfaction, and quality of life issues. It is one of the most significant developments in recent decades because of its comprehensive approach to measuring care for the patients that we serve.”

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Facilitating Outcomes Research in O&P
Stefania Fatone, Ph.D.

Since 2007, Stefania Fatone, Ph.D., BPO(Hons), and Steven A. Gard, Ph.D., have been members of the Orthotics and Prosthetics Outcomes Initiative Steering Committee sponsored by the American Orthotic and Prosthetic Association (AOPA) with the collaboration of the American Academy of Orthotists and Prosthetists (AAOP). The mission of this committee is to facilitate outcomes research in the field of prosthetics and orthotics. One of the tasks that the committee addressed was to identify topics that required outcomes and those for which outcomes already were available. The committee determined that the orthotic management of stroke fulfills those criteria. While this topic has received considerable attention in the past, the committee agreed to undertake the additional work to develop and disseminate this information expressly to educate and inform O&P professionals.

The committee recommended the development of an Evidence Note to update relevant information about the management of stroke and also incorporated specific information about the use of ankle foot orthoses (AFOs). On behalf of the committee, Stefania Fatone, Ph.D., with the assistance of James Campbell, Ph.D. (Becker Orthopedics), led the development of the first Evidence Note, “The Use of Ankle Foot Orthoses in the Management of Stroke.” This Evidence Note is freely available in PDF format from the AOPA website at http://aopanet.org/press/research.php.

Learn more about Evidence Notes at AOPA:

Enhancing the Quality of P&O

Dennis Hart, Ph.D., PT, of FOTO added, “People who get on board now with outcomes will be ahead of the curve in the future when outcomes become standard practice within the field of prosthetics and orthotics.”

Designed for use in clinical settings, the Outcomes Management Project offers prosthetists and orthotists cost effective ways to implement outcomes measures for P&O patients and facilities. Informed changes in practice can improve P&O patient care and boost compliance with ABC’s Performance Management and Improvement Standards. This project standardizes procedures, database and outcome measures; and provides an online educational component that P&O practitioners can use in compliance of ABC practice standards, thus enhancing the welfare of persons living with disabilities.

References:
The First Decade

The Department of Veterans Affairs and the Department of Defense (VA/DoD) have worked together since 1998 to adapt internationally recognized Clinical Practice Guidelines (CPGs). The Institute of Medicine defines CPGs as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”

During the past decade, the VA and DoD have developed, launched and updated a series of CPGs that have improved the quality of care and health management across both systems. CPGs also have become standard in the private sector. The U.S. Army serves as the DoD’s lead for all CPG initiatives and collaborates with the Navy and Air Force, as well as with the Veterans Health Administration to develop multidisciplinary guidelines about evidence-based practice that meet military and veteran medical requirements. CPGs are related to re-deployment issues with respect to Rehabilitation of Lower Limb Amputation, Post Traumatic Stress Disorder and other conditions.

CPGs Ensure Quality of Care

Kenneth W. Kizer, M.D., MPH, who served as the VA Undersecretary for Health (1994-1999), was instrumental in using performance measurements to improve the VA health care system. In 1997, Dr. Kizer noted, “Guidelines are an important clinical strategy to build quality of care into our system…, assure the appropriate amount of care, reduce errors and promote patient safety, ensure predictable and consistent quality, promote learning and research, and facilitate patient and family education.”

VA and DoD initiated programs to educate clinical practitioners about the value of using CPGs. Ongoing education has provided CPG training manuals that accompany direct and on-line education programs. Web-based CPG references provide instant access to information, guidance, and related links about VA/DoD CPGs. Tracking and measuring compliance with guidelines showed improvements in the quality and uniformity of health care throughout the VA/DoD systems.

Updating CPGs

Based on the state of the science, new CPGs are established and existing CPGs are reviewed, updated or retired. VA and DoD health care facilities engage all levels of care to gather and report feedback about evidence-based protocols. Timely data are solicited from physicians, nurses, allied health care personnel, and patients. Compliance is supported with multiple strategies such as computerized reminders, surveys, and self-reports. The VA and DoD find that collecting longitudinal data reinforces team effort and accountability. These data refresh CPGs with respect to 1) process (examinations and tests); 2) health outcomes (morbidity, mortality and functional status); and 3) patient satisfaction with access and quality of care.

Current Status

Today, physicians, allied health professionals such as prosthetists and orthotists, treatment facilities, public agencies, and insurers alike accept CPGs as indispensable for delivering appropriate health care. Public access, on-line CPGs may cross-reference conditions with research, references and URL sites. During the past decade, evidence based clinical practice, as represented by the use of CPGs, has enabled clinicians to improve the quality and uniformity of care that is provided throughout the VA/DoD medical facilities and beyond.

References:

James L. Del Bianco, BSE, graduated from NUPOC’s orthotics certificate course in 2006 and subsequently completed his residency research project at NURERC under the guidance of Stefania Fatone, Ph.D., BPO(Hons). He co-authored with Dr. Fatone a case report, “Comparison of Silicone and Posterior Leaf Spring Ankle-Foot Orthoses in a Subject with Charcot-Marie-Tooth” and submitted it to the National Commission on Orthotic and Prosthetic Education (NCOPE) in fulfillment of his Directed Study requirement. This research has been recognized by the American Academy of Orthotists and Prosthetists (AAOP) as the Best of the Resident Directed Studies for 2008. Currently, Mr. Del Bianco is affiliated with the Department of Prosthetics and Orthotics, University of North Carolina Hospitals, Chapel Hill, NC. NURERC will continue to work with Mr. Del Bianco, who has agreed to participate as a clinical collaborator on a NIDRR funded orthotics outcomes project.

At NURERC, Mr. Del Bianco and Dr. Fatone examined the most appropriate orthotic management of a 49-year old male patient with Charcot-Marie-Tooth (CMT), type Ix. CMT is the most commonly inherited neurological condition; and CMT patients often require orthotic management due to bilateral lower limb weakness and neuropathy distal to the knees. This case study compared three conditions while the subject walked at his normal, self-selected speed over level ground, wearing in turn 1) shoes alone, 2) bilateral silicone ankle-foot orthoses (SAFOs), and 3) thermoplastic posterior leaf spring AFOs (PLS-AFOs).

Results indicated that compared with shoes only, gait improved with both SAFOs and PLS-AFOs; however, the greatest degree of improvement occurred with the PLS-AFOs, despite greater restriction in ankle range of motion. The PLS-AFOs corrected gait deviations in both stance and swing phases; whereas the SAFOs affected primarily ankle kinematics in swing phase. During the loading response phase, the PLS-AFOs increased the peak internal dorsiflexion moment, whereas the SAFOs had almost no effect during this phase. When compared with the shoe-only condition, the PLS-AFOs provided most toe clearance during swing phase by increasing mid-swing dorsiflexion, while the SAFOs provided comparatively less toe clearance. In late stance, both orthoses produced the same magnitude of knee hyperextension. Possibly, limiting tibial progression transfers forward momentum to the thigh, which the weakened gastrocnemius cannot restrain.

Comments elicited from the subject indicated that, despite consciously having to raise his toes during swing, the SAFOs were more comfortable than the PLS-AFOs. Also, he preferred the SAFOs for tennis and walking on uneven terrain because they seemed to conform to the surface and provided better balance than the PLS-AFOs.

Results of this study suggest that clinicians should not expect the SAFO to perform in the same manner as a thermoplastic PLS-AFO during level, over-ground walking, and that use of the SAFO seems appropriate for persons with gait deviations that are limited to mild equinus during swing phase.

References:

Acknowledgements:
Funds from the National Institute on Disability and Rehabilitation Research (NIDRR) of the U.S. Department of Education under Grant H133E030030 supported this work. The opinions in the publication are those of the grantee and do not necessarily reflect those of the U.S. Department of Education. The authors acknowledge the use of the VA Chicago Motion Analysis Research Laboratory of the Jesse Brown VA Medical Center, Chicago, IL.

Eugene P. Lautenschlager, Ph.D., Passes

Eugene Lautenschlager, Ph.D., known to his friends and colleagues as Gene, passed away in March 2009. He earned his doctorate in Materials Science at Northwestern University (1966) and continued at NU to become full professor, serving in the Dental School and Biomaterials Science and Engineering. From 1988 Dr. Lautenschlager served as the Director of Biological Materials at NU. He translated his knowledge of dental materials to orthopedic surgery, medical implants, limb prosthetics and many other areas. He held eight patents on dental and medical materials and devices, published widely and was the recipient of many honors and awards, including the International Fellow of Biomaterials Science and Engineering conferred by the Society for Biomaterials (2000).

A long time colleague of Dr. Lautenschlager, Dudley S. Childress, Ph.D., reflected, “I remember Gene as a singer, speaker and raconteur. I’ll miss this loquacious guy who has added so much to the understanding of biomaterials and how they can be used to change aspects of the world in positive ways.”
The Reciprocating Gait Orthosis (RGO) allows people with lower limb paralysis to walk. In RGOs, a reciprocal link is used to couple the two hips to create a reciprocal gait pattern. Walking in a Reciprocating Gait Orthosis is slow and exhausting, and the high energy requirements of RGO use have been cited as a major factor in its limited use and eventual abandonment. Therefore, in order to encourage people with lower limb paralysis to use RGOs and enjoy the therapeutic and psychosocial benefits of upright ambulation, it is essential to reduce these energy requirements. Analysis of the gait dynamics of RGO users provides valuable data that may improve the efficiency of walking with RGOs.

As partial fulfillment of this goal, we obtained the informed consent of five RGO users and used a marker-based motion capture system and force plates embedded in the floor to measure their body kinematics and kinetics, respectively. We found that RGO users bore more than half of their body weight through their arms during portions of the single support phase of gait. We also found that RGO users walked with a flexed trunk throughout the gait cycle, but extended it during portions of single support. Our data showed that the power generated by the reciprocal link during swing was small compared to other driving forces of leg swing. During the latter half of swing phase, posterior forces acted on the RGO users’ stance foot and walking aides. Lastly, we observed poor conservation of the trunk’s mechanical energy.

We hypothesized that the large amount of arm bearing is caused by the motion of the RGO users’ trunks and posit that it contributes to their high energy expenditure. We concluded that the reciprocal link contributes very little to leg swing; however, we hypothesized that increasing the contribution of the reciprocal link to leg swing may help improve the efficiency of RGO gait. We also hypothesized that poor conservation of the trunk’s mechanical energy contributes to high energy expenditure and is caused by the posterior forces acting on the users’ stance foot and walking aides during the latter half of single support phase.

As part of my future work, I intend to test these hypotheses.

**Making Strides with the RGO**

William B. Johnson, M.S.

Through educational programs, NURERC staff and students annually disseminate information about rehabilitation engineering to the public. On February 28, Craig Heckathorne, M.Sc., Stefania Fatone, Ph.D., BPO(Hons), and Kiki Zissimopoulos, M.S., presented 3 seminars about rehabilitation engineering research in the area of prosthetics and orthotics to young women who attended the 38th Career Day for Girls. Co-hosted by the Northwestern University McCormick School of Engineering and the Society of Women Engineers (SWE), NURERC participates annually in this event to inform female pre-college students about career opportunities in rehabilitation engineering.

Approximately 50 young women from Illinois middle, junior and high schools attended this presentation to learn about prosthetics and orthotics from the perspectives of education, research and clinical application. Using a variety of hands-on prostheses and orthoses, Mr. Heckathorne and Dr. Fatone discussed their purpose and function. Students were avidly interested in using the demonstration model of a myoelectric upper limb prosthesis and their questions showed the value of early guidance toward a rehabilitation engineering path. Ms. Zissimopoulos, a Ph.D. candidate in bioengineering who also has been trained in Orthotics at NUPOC, explained ways that women can combine a career in biomedical engineering with clinical and academic disciplines.
Appointments
Steven A. Gard, Ph.D., has been invited to serve on the Board of Associate Editors for the Journal of Rehabilitation Research & Development (JRRD) published by the Department of Veterans Affairs. Dr. Gard has served on the JRRD Editorial Board since 2002.
Andrew Hansen, Ph.D., and Stefania Fatone, Ph.D., BPO(Hons), have been invited to serve on the American Academy of Orthotists and Prosthetists (AAOP) Orthotics & Prosthetics Education and Research Foundation Scientific Committee.

Meetings
Stefania Fatone, Ph.D., BPO(Hons), attended a meeting of the Prosthetic and Orthotic Outcomes Initiative Steering Committee of the American Orthotic & Prosthetic Association (AOPA), held in Washington, DC, on January 28. Steven A. Gard, Ph.D., also a member of this committee, participated in the meeting via conference call.
Andrew Hansen, Ph.D., attended a training session for the NeuroCom® Balance Manager® SMART EquiTest® Clinical Research System™ in Seattle, WA, on January 28-30.
Steven A. Gard, Ph.D., Stefania Fatone, Ph.D., BPO(Hons), and William B. Johnson, M.S., attended the 35th Annual Meeting and Scientific Symposium of the American Academy of Orthotists and Prosthetists (AAOP) in Atlanta, GA, on March 4-7.
Craig Heckathorne, M.Sc., attended the annual training meetings in Effingham and Peoria, IL for Illinois’ AgrAbility ambassadors on March 11-12. He attended these meetings as part of the NIDRR funded project “Assessing and Responding to the Prosthetic Needs of Farmers and Ranchers.”

Presentations
Steven A. Gard, Ph.D., and Stefania Fatone, Ph.D., BPO(Hons), presented papers at the American Academy of Orthotists and Prosthetists (AAOP) Annual Meeting. Steven A. Gard, Ph.D., taught a 2-hour graduate class and presented “Developing World Prostheses.”
Andrew Hansen, Ph.D., was invited to present “Roll-over Shapes of Lower Limb Systems and Their Clinical Implications for Prosthetics and Orthotics” at the Mayo Clinic College of Medicine Biomedical Engineering Seminar on January 16.
Dr. Hansen again presented this talk at the Media Laboratory (Biomechatronics) at the Massachusetts Institute of Technology (MIT) on February 18. Also he taught a 2-hour graduate class and presented “Developing World Prostheses.”
Dr. Hansen gave an invited presentation titled “Rockers and Rollers” to approximately 40 faculty who attended the Quarterly Faculty Meeting for the Northwestern University Department of Physical Medicine and Rehabilitation, the Feinberg School of Medicine on February 24.
Sara Koehler, M.S., discussed innovations in prosthetics engineering in “What’s New in Rehabilitation Research” presented at the Annual Nancye B. Holt Management Course: Challenges in Leadership and Management sponsored by the Rehabilitation Institute of Chicago (RIC) on March 6.

Visitors
Matt Doering (Blatchford, USA) and Joe McCarthy (Blatchford, UK) visited NURERC on December 16-17, 2008 to exchange information about projects of mutual interest and to introduce new products, including the Echelon Foot®, an adaptable ankle-foot system that provides ankle dorsiflexion and plantar flexion.
Jerome Rifkin of Tensegrity Prosthetics Inc. (Louisville, CO) visited NURERC to learn about the Shape&Roll Prosthetic Foot on February 2.
Steven A. Gard, Ph.D., conducted a tour of NURERC laboratories on February 18 for representatives from Otto Bock. Representatives included Andreas Kanneberg, M.D., Medical Director of Otto Bock International; Dr. Milana Mileusnic, Clinical Trials Manager (Vienna); and Ms. Kimberly Walsh, Director, Clinical Research (USA). Dr. Gard and the Otto Bock group discussed possible future collaborations.

NURERC hosted an educational laboratory tour for students who are enrolled in the prosthetics course at NUPOC. Students visited four sites within the Prosthetics Research Laboratory to learn about rehabilitation engineering research. Craig Heckathorne, M.Sc., discussed upper limb prosthetics; Charles Wang, B.S., discussed the Shape&Roll Prosthetic Foot that is available to low-income countries as a self-sustainable device; Kerice Tucker, research engineer, discussed CAD-CAM and rapid prototyping; and Stefania Fatone, Ph.D.(Hons), Rebecca Stine, M.S., and Brian Ruhe, M.S., discussed gait analysis in the VA Chicago Motion Analysis Research Laboratory (VACMARL).
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