

CSP Newsletter



Volume 6, Issue 3, September 2015



Highlight on CSP #2003

By: Gary Frazier, Project Manager, CSP Perry Point

As an Army Medic at Aberdeen Proving Grounds, MD, I often found myself on the campus of the old Walter Reed Army Medical Center (WRAMC) in Washington, D.C. WRAMC hosted one of the largest wounded warrior programs for soldiers returning from the battlefields of Iraq and Afghanistan. As I passed through the campus I would often see young men and women paralyzed and wheelchair-bound by their injuries. I thought about how horrible it would be to lose the ability to walk, and how fortunate I was to not be in a similar situation. To be so young, with your whole life in front of you, and to literally have your legs taken out from under you is a devastating reality for far too many of our nation's Veterans. As the reality sinks in, depression often follows. But what if these men and women, Veterans of our nation, could walk again?

Advances in the field of exoskeleton technology are making it possible for our Veterans to walk again. On June 26, 2014, the Food and Drug Administration (FDA) cleared the way for the first Personal Exoskeleton System for use in the home and the community, the ReWalk Robotics Personal System. While this technology has been around for several years in the hospital setting and has been cleared for home use in Israel and Europe, this is the first time in the United States that an exoskeleton has been authorized for use outside of a hospital/rehabilitation setting.

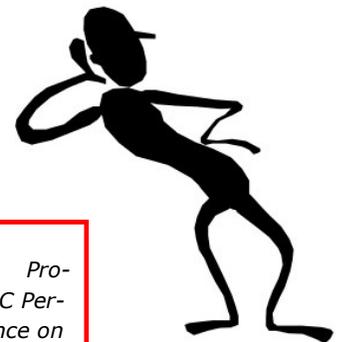
Our nation's Veterans who have incurred spinal cord injuries (SCI) resulting in paralysis deserve the best care available, and any advances in research and technology need to be applied to our Veterans' standard of care as quickly and safely as possible. If approved, CSP #2003 "Exoskeletal-Assisted Walking in Persons with SCI: Impact on Quality of Life" would be instrumental in determining what benefits, if any, exist for our Veterans using the exoskeletons in their homes and communities. The study Chair, Dr. Ann Spungen, is a highly regarded researcher in the field of SCI and exoskeletal-assisted walking. The study team at Perry Point, led by Biostatistician Karen Jones, is looking forward to providing the support necessary to design, implement, and provide the analysis for a highly successful study. I am honored and humbled at the opportunity to work on a trial with the potential for such significant implications to the daily lives of our country's heroes who suffer from SCI and the loss of their mobility.

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Pictured at left Suad El Burai Felix, MPH, Statistical Programmer in the Data Management Section at CSPCC Perry Point. Suad attended the 2015 National Conference on Health Statistics Poster Session and presented a poster titled "Asthma Prevalence Among Hispanic Adults in Puerto Rico and Hispanic Adults of Puerto Rican Decent in the United States Results from Two National Surveys." She presented the poster during the conference on August 25, 2015 in Bethesda, MD.



CSP Publications & Presentations

Durham CSPEC

Johnson MR, Grubber J, Grambow SC, Maciejewski ML, Dunn-Thomas T, Provenzale D, Fisher DA. "Physician Non-Adherence to Colonoscopy Interval Guidelines in the Veterans Affairs Healthcare System."
Gastroenterology 2015 Jun 26; PII:S0016-5085(15)00885-9.DOI: 10.1053/J.GASTRO.2015.06.026 [Epub Ahead of Print]

Hines CSPCC

Matsumura JS, Stroupe KT, Lederle FA, Kyriakides TC, Ge L, Freischlag JA. "Costs of Repair of Abdominal Aortic Aneurysm with Different Devices in a Multicenter Randomized Trial."
Journal of Vascular Surgery. 2015 January; 61(1):59-65.e2 (DOI:10.1016/j.jvs.2014.08.003)

Florez H, Reaven P, Bahn G, Moritz T, Warren S, Marks J, Reda D, Duckworth W, Abaira C, Hayward R, Emanuele N from the VADT Research Group. "Rosiglitazone Treatment and Cardiovascular Disease in the Veterans Affairs Diabetes Trial."
Diabetes, Obesity and Metabolism. Published online 2015 June 17. (DOI: 10.1111/dom.12487)

Hayward RA, Reaven PD, Wiitala WL, Bahn GD, Reda DJ, Ge L, McCarren M, Duckworth WC, Emanuele NV. "Follow-up of Glycemic Control and Cardiovascular Outcomes in Type 2 Diabetes."
New England Journal of Medicine. 2015 June 4; 372(23):2197-2206. (DOI: 10.1056/NEJMoa1414266)

Katz M, San Luciano M, Carlson K, Luo P, Marks WJ, Larson PS, Starr PA, Follett KA, Weaver FM, Stern MB, Reda DJ, Ostrem JL and CSP 468 Study Group. "Differential Effects of Deep Brain Stimulation Target on Motor Subtypes in Parkinson's Disease."
Annals of Neurology. 2015; 77:710-719. (DOI: 10.1002/ana.24374)

Pharmacogenomics Analysis Laboratory, Little Rock, AR

Logue MW, Smith AK, Baldwin C, Wolf EJ, Guffanti G, Ratanatharathorn A, Stone A, Schichman SA, Humphries D, Binder EB, Arloth J, Menke A, Uddin M, Wildman D, Galea S, Aiello AE, Koenen KC, Miller MW. "An Analysis of Gene Expression in PTSD Implicates Genes Involved in the Glucocorticoid Receptor Pathway and Neural Responses to Stress."
Psychoneuroendocrinology. 2015 Jul;57:1-13. [doi:10.1016/j.psyneuen.2015.03.016]

Perry Point CSPCC

Novitzky D, Mi Z, Collins JF, and Cooper DKC. "Increased Procurement of Thoracic Organs After Thyroid Hormone Therapy—Analysis of 63,593 Brain-Dead Donors."
Seminars in Thoracic and Cardiovascular Surgery (in press)

Mi, Z, Krystal JH, Jones KM, Robert A, Rosenheck RA, Joseph JF, and Lu Y. "Statistical Assessment of Rescue Medication Effect in Psychiatric Clinical Trials." The Society of Clinical Trials 36th Annual Meeting, 2015, Arlington, VA.

West Haven CSPCC

CSP #565, VA NEPHRON-D STUDY

Leehey DJ, Zhang JH, Emanuele NV, Whaley-Connell A, Palevsky PM, Reilly RF, Guarino P and Fried L. "Blood Pressure and Renal Outcomes in Diabetic Kidney Disease: Results From the VA NEPHRON-D Trial."
Accepted by the Clinical Journal of the American Society of Nephrology.

Coaching Highlight:

Trained Gallup Strengths coaches across the program are collaborating to help the Million Veteran Program (MVP) implement strengths-based coaching. Approximately 50 MVP site teams will be offered the opportunity to engage in virtual team coaching sessions with one of several participating coaches. During coaching, site teams will explore their natural talents and may identify additional ways to apply their strengths to approved recruitment strategies.

With Respect and Honor We Thank You
VETERANS!

Hines CSPCC on ELinORE

The Engaging Life in Our Research Employees (ELinORE) was founded in June 2015 as an employee lead committee to support professional, social, and operational activities for Hines CSPCC. Current members are Tom Sindowski, Lisa Robin, Marie Reinhard, Carol Oswald, Gideon Bahn, Elinore (just a coincidence) Sheryka, Jim Steward, and Cheryl Odle. However, the meetings are open door, and any staffer is welcome to participate when their schedule permits. The ELinORE meets every Friday at 10 a.m. and even has a mascot!

The goal of The ELinORE is to facilitate a fun and informative environment for our employees through engaging in social activities, wellness promotion, professional development, and the promotion of employee-centered processes.

To date, our events and activities have included an ice cream social (below), farewell party for Statistical Programmer Charlie Spanbauer, and employee On the Spot Award presentations. Upcoming scheduled events include a Cross Town Classic picnic (when you have two baseball teams in your city, there tends to be some rivalry) and a "Guess Which President's Birthday It Is?" monthly challenge.

The ELinORE is also working on a proposal for local management to improve performance evaluation processes to promote greater employee involvement.



Brought to you by The E.L.inO.R.E

CSP STUDY UPDATES

CSP #468, "A Comparison of Best Medical Therapy and Deep Brain Stimulation of Subthalamic Nucleus and Globus Pallidus for the Treatment of Parkinson's Disease," has closed out and is in final study analysis.

CSP #571, "Drug-Eluting Stents vs. Bare Metal Stents In Saphenous Vein Graft Angioplasty (DIVA)," will be holding an in-person Data Monitoring Committee (DMC) Meeting on October 13, 2015.

CSP #576, "VA Augmentation and Switching Treatments for Improving Depression Outcomes (VAST-D)," held their Annual Meeting on May 28-29, 2015 in Dallas, TX.

CSP #577, "Colonoscopy vs. Fecal Immunochemical Test in Reducing Mortality from Colorectal Cancer (CONFIRM)," held their Annual Meeting on June 2-3, 2015 in Orlando, FL. (See photo on page 4 of newsletter.)

CSP #588, "Randomized Endo-Vein Graft Prospective," will hold an Annual Meeting on October 20-21, 2015 in Albuquerque, NM.

CSP #591, "CERV-PTSD: Comparative Effectiveness Research in Veterans with PTSD," held its Annual Meeting on July 30, 2015 in the San Francisco area.

CSP #596, "Optimal Treatment for Recurrent Clostridium Difficile Infection," received Central IRB approval and is currently planning a rolling Kickoff Meeting for Fall 2015.

CSP Perry Point, "Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD," held a Data Monitoring Committee (DMC) Meeting in July 2015.

VA/NIDA CSP #1032, "AZD8529 for Smoking Cessation: A Phase 2 Study," initiated screening activity within the Medidata eDC system in mid-July 2015.





A Behind the Scenes Thank You!

*Provided By: Tara Burke, Health Systems Specialist,
CSPCC Perry Point*

CSP is composed of innovators, risk takers, and committed team players always ready and willing to get the job done both timely and with the highest quality. This is just a brief note to remind everyone that what we do is important and we are good at it!

A huge thank you to the staff who come in early or stay late, who work through lunch breaks and schedule around meetings, who take time to train, help, share, mentor, or support their team members. To all of the staff who are the Cooperative Studies Program (CSP), thank you for your dedication and hard work.

To the ones who do things because they need to be done, not because it's an SOP or WI, but simply because you care enough to take on tough projects and challenges. We should all be thankful for each of our team members for encouraging us, supporting us, and sharing positive vibes.

With so many different functional groups and roles that CSP is composed of, we all need a pat on the back for working as a team and always being willing to volunteer. Thank you to the team members who are always willing to go the extra mile. Thank you to the behind the scenes folks, whether you are on study teams, subdomains, working groups, making travel possible, managing our budgets, operations, supervisors, leads or managers, maintaining and keeping TMS records, printing, or simply doing "other duties as assigned."

Thank you.

Organized Office Results to Improving Productivity

*By: Suad El Burai Felix, Statistical Programmer,
CSPCC Perry Point*

While organizing my office this past week I found the handouts of a webinar I took at the beginning of this year about "Organizing for Productivity." Reading through it, the speaker, Laura Beck, LCSW, emphasized that disorganization in the workplace induces stress of preoccupation with tasks, poor task pacing, stimulus overload, lack of skills, and psychological obstacles. She pointed out "time wasters" such as procrastination, poor planning, interruptions, etc.

After reading and reflecting upon it I saw the connection of the webinar content with the lean approach, which encourages aiming for ongoing improvement, providing quality services, and increasing productivity. Time wasters are one of the challenges we want to overcome when applying a lean process of thinking. Exploring online I was able to find two interesting articles: "Productivity and Organizing Insights Found in Lean Systems," by Erin Doland, and "5S: A 5-Step Approach to Getting Your Office Organized," by Andrey Thomas. (*Links listed below.*) I have summarized Andrey Thomas' advice on practical ways to organize your office and to overcome waste resulting in improving productivity.

5S Lean Processes

1. Sort

When in doubt, move it out: Clutter is the result of postponing decisions, so decide what needs to stay and what needs to go.

2. Straighten

Put everything in its place: Designate the best area to place specific items.

3. Shine

To be lean, you must clean: A clean space ensures quality and efficiency, and you will be more motivated to come to work.

4. Standardize

Make routine become habit: Standardization results in efficiency, reduces errors, and increases productivity.

5. Sustain

Make it simple to sustain: As you keep an organized environment it will be easier for you to maintain it.

Let's start integrating these simple steps to get more organized, as it will ultimately rebound in a more productive environment.

Productivity and Organizing Insights Found in Lean Systems:
<https://Unclutterer.com/2009/01/14/Productivity-and-Organizing-Insights-Found-in-Lean-Systems/>

5S: A 5-Step Approach to Getting Your Office Organized:
<http://www.Bizjournals.com/bizjournals/How-to/Hrowth-Strategies/2014/06/5s-5-Step-Approach-to-Organized-Office.html?page=all>

CSP #577 Annual Meeting photo, mentioned in Study Updates on page 3.



CSP Personnel Updates

Albuquerque CSPCRPCC

Shirley Madrid, Chief of Quality Management, just got a little leaner-Yellow Belt Lean, that is. She completed the VA's White Belt Training and followed up with the Yellow Belt Training for certification as part of her Leadership Development Institute requirements. She graduated from the VISN 18 LDI Program on August 27, 2015. For more information on the VA's Center for Health Engineering, visit their SharePoint site: <http://vawww.srkms.portal.va.gov/ASRSVERC/CHE/Pages/default.aspx>. Upcoming classes are posted on the training calendar to help improve the health and wellbeing of Veterans through application of systems engineering principles and tools.

The PCC mourns the loss of a much loved co-worker, Patricia Ehlinger, Budget Analyst. Pat passed away on Friday, July 31, 2015. During her 27 years with our center she was not only a dedicated employee but also filled the roles of mentor and championed many innovative ideas and solutions. Outside of work, Pat was an avid animal rights activist, hiker, passionate kayaker, drummer, and mandolin instructor whose favorite song was "Ho Hey." She was a kind and patient individual with a ready smile or practical joke. She has left a huge gap in our hearts and our lives, but, as was so typical of Pat, it is with a smile that we remember she left us on a blue moon.

Durham CSPEC

MaryBeth Grewe joined the CSPEC on April 20, 2015 as a Project Manager. She graduated in 2014 with a Master of Public Health in Health Behavior from the University of North Carolina at Chapel Hill and spent the last year working as a Senior Research Assistant at the UNC School of Medicine. She has a strong background in qualitative research and is excited to expand on her research skills at CSPEC.

Meghan O'Leary has recently joined the CSPEC as a Project Manager for the CSP #380 and CSP #500 studies (500A/B) and started on April 20, 2015. Meghan comes to the CSPEC from the non-profit organization Feeding America, where she conducted food insecurity research. She also previously focused on research regarding health information needs among cancer patients as a Research Assistant at the University of New Mexico Cancer Center.

Kristina Felder joined the CSPEC on April 20, 2015 and will be working as a Research Assistant. She graduated in 2014 with an MPH in Health Behavior from the University of North Carolina at Chapel Hill, and worked at a local non-profit as a case manager for domestic violence victims prior to coming to the center. She also previously worked as a Research Assistant with Cervical Cancer-Free North Carolina, and is looking forward to using her qualitative research skills to contribute positively to the CSP #585 project.

Kudos to Becky McNeil, Lead Biostatistician for the CSPEC Computational Sciences Core, who received funding for her HSR&D proposal, "Healthcare Utilization and Associated Costs for Gulf War I Era Veterans." After working with CSP #585 (the Gulf War Era Cohort and Biorepository) for more than five years, Becky was overcome with inspiration for potential uses of the Cohort's data to learn more about the current disease burden, utilization patterns, and patient perspectives on healthcare within this population. This three-year mixed-methods project, scheduled to begin in October of 2015, will nurture growing ties between HSR&D and CSP, and includes several co-investigators from both HSR&D and the CSPEC. Please contact Becky if you are interested in any applied or methodologic research collaborations related to this project.

Hines CSPCC

Statistical Programmer Charlie Spanbauer, M.S., has left to pursue his Ph.D. at the Medical College of Wisconsin, Milwaukee. Charlie's Hines colleagues wished him the best with a Wisconsin-themed farewell party.

Several Hines center staffers received the On the Spot Award, where Hines VA Hospital personnel nominate their co-workers for making contributions in support of the VA's Strategic Plan. Receiving the award for summer 2015 were Vicky Barillas, Mary Biondic, Rodney Brown, Kim Carlson, Barbara Christine, Mike Klein, Dan Lippe, Carol Oswald, Raslan Othman, Shirley Phillips, Maria Rachelle, Marie Reinhard, Lisa Robin, Elinore Sheryka, and Kelly Tir.

Palo Alto CSPCC

Congratulations to Iiana Belitskaya-Levy, Biostatistician, who had a beautiful baby boy on August 12, 2015. Levy was born weighing in at 8 pounds and 12 ounces. Both Mom and baby are doing wonderfully. *(pictured right)*

West Haven CSPCC

West Haven CSPCC has hired several new employees over the past few months. Sakasha Taylor and Roderick Jones were hired as Office Automation Assistants. Hairong Huang was hired as a Program Analyst, Linda McDonald was hired as a Quality Assurance Nurse Specialist, and Dea Papajorgji-Taylor was hired as a Project Manager.



Quality Notes

ISO 9001:2008 Requirement for Records Control

By: Kim DiBenedetto-Rogers, QM Subdomain

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records. Records shall remain legible, readily identifiable, and retrievable.

Our current document procedure, SOP 9.7, Control of Quality Records identifies these ISO requirements. Each individual SOP should identify the storage and retrieval method and the location of the records. The storage and retrieval methods will be the same. If the record is stored off site, a local document procedure must outline how to retrieve such record. For the retention and disposition of records we must follow National Archives and Records Administration (NARA) Records Schedule.

If you have any questions or concerns related to control of records, please see your local Quality Specialist.

Topic Discussions from the Quality Management Subdomain:

- ◆ Quality should be a part of life and should come naturally.
- ◆ ISO is just a tool used to ensure quality but Quality is the Principle.
- ◆ Don't just do what is told of you; understand what you are doing and why it is important to achieve quality while doing it.
- ◆ Achieving performance excellence in data integrity, complying with requirements, and in customer service goes beyond quality ... Let's apply performance excellence to our daily activities!

PCC Employees Named as Examiners for 2015 Malcolm Baldrige National Quality Award

The Commerce Department's National Institute of Standards and Technology (NIST) named Stan Johnson, Chief of Quality Control, and Shirley Madrid, Chief of Quality Management, to the Board of Examiners for the 2015 Malcolm Baldrige National Quality Award. Mike Sather, PCC's former Director, continues his 3-year appointment on the Judges Panel. The Baldrige Award is the nation's highest honor for organizational innovation and performance excellence.

Appointed by the NIST Director, examiners are responsible for reviewing and evaluating applications submitted for the Baldrige Award, as well as other assessment-related tasks. The examiner board is composed of more than 350 leading experts competitively selected from industry, professional, trade, education, healthcare, and nonprofit (including government) organizations from across the United States. In total, seven members are VA employees.

Those selected meet the highest standards of qualification and peer recognition, demonstrating competencies related to customer focus, communication, ethics, action orientation, team building, and analytical skills. All members of the board must take part in a nationally ranked leadership development course based on the Baldrige Criteria for Performance Excellence and the scoring/evaluation processes for the Baldrige Award.

HSS Site Visit

The Boston CSPCC/MAVERIC was kind enough to host an HSS Site Visit to its Center over July 16 & 17 led by Lauren Weil. Attendees included: Wanda UMBER from the Albuquerque CSPCRPCC, Jen Sporleder, Sara Kath from the Seattle ERIC, and Cheylynne Bosley-Somogyi from the Palo Alto CSPCC. During the visit the group discussed a wide range of topics including the differences in HSS responsibilities across the program; HSS ongoing projects and strategic planning; and the role of Boston's project managers on CSP studies. There were also SharePoint demonstrations and time for questions and answers with Boston's SharePoint experts; and informative discussions on the interactions and collaborations between Epidemiological Centers and Coordinating Centers. The group got a tour of the Biorepository and had individual meetings with staff to discuss ongoing projects. We would like to thank the Boston CSPCC/MAVERIC for hosting us and for all the staff members who took time out of their busy schedules to meet with us.

During the evening of July 16, Lauren Weil arranged for dinner in downtown Boston and a tour of the city on Boston's Original and World Famous Boston Duck Tours. The Duck Tour provided a great overview of the city, showed unique neighborhoods, many historic landmarks and splashed us into the Charles River for amazing views of the Boston and Cambridge skylines while we avoided sailboats, kayakers, other "Ducks," and everyone else out on the water for the evening.



Pictured above during the HSS Site Visit are (L to R): Lauren Weil, Cheylynne Bosley-Somogyi, Sara Kath, Jen Sporleder, and Wanda UMBER.



CERC Welcomes Dr. Krishnan Radhakrishnan

The Clinical Epidemiology Research Center (CERC), West Haven, CT, welcomes Dr. Krishnan Radhakrishnan, M.D., Ph.D., M.P.H., as the CERC Epidemiologist. Prior to joining CSP, Dr. Radhakrishnan served as chief resident in the general preventive medicine and public health residency program at University of Kentucky, Lexington, where he also earned an M.P.H. with a concentration in epidemiology. As an American Cancer Society Fellow, his work focused on cancer prevention and control. He previously had worked at the NIH-supported New Mexico Center for the Spatiotemporal Modeling of Cell Signaling, where his research focused on mathematical and computational modeling.

Dr. Radhakrishnan's career path has been anything but traditional. At a very early age (and as a son of a mathematician) he showed strong aptitude for mathematics and the physical sciences, and was guided toward a career in engineering. He graduated with honors from Imperial College, London, and then moved to the United States to pursue graduate education. After earning an M.S. from Cornell and a Ph.D. from MIT, Dr. Radhakrishnan conducted research at NASA's Glenn Research Center, focusing on mathematical/computational modeling of combustion, with applications in aero and space propulsion. Dr. Radhakrishnan later adapted these physicochemical numerical methods to model the chemical pathways arising in human metabolism and cell signaling.

When his mother experienced health problems, Dr. Radhakrishnan performed extensive research to understand her condition. This experience rekindled a long-standing interest in medicine, and demonstrated to him the importance of clinical practice in medical research. Returning to school, Dr. Radhakrishnan earned his M.D. degree from Case Western Reserve University. His career path then took him back to NASA, where he collaborated on several projects involving retinal vascular remodeling, both in diabetic patients and in astronauts after long-term spaceflight. This work led to discoveries in early-stage vascular remodeling that are being investigated further with a new NIH-supported study of diabetic retinopathy. The corresponding retinal vascular analytic methods are also being explored for applications in assessing visual complications associated with traumatic brain injury.

Dr. Radhakrishnan now brings his varied and interdisciplinary research experience to CERC. In addition to being the project lead for CSP #575B, a genome-wide association study that is linked to the Million Veteran Program (MVP), he also serves as a key team member for other CERC projects, including CSP #566 ("non-genomic" study of PTSD), CSP #572 (genomic study of schizophrenia and bipolar disorder), and CSP #2006 (genomic study of Gulf War Illness).



While 2 million people partied in Chicago over the Blackhawks' third Stanley Cup win in six years, the CSPCC Hines Center staff were on the job. Staff marked the occasion by wearing Hawks colors; pictured (from left to right) are Mike Klein, Kim Carlson, Maria Rachelle, Tom Sindowski, Lisa Robin, Elinore Sheryka, Carol Oswald, Michelle Johnson, and Vicky Barillas. Pictured right is Lisa's daughter, Eva, hoisting up the Cup in celebration of the National Hockey League Champions.



NEWSLETTER TEAM: Mercedes Andino, Heather Buckland, David Burnaska, Sandra Dixon, Marcus Johnson, Michael Klein, William Lance, Dan Lippe, Veronica Natividad, Shirley Phillips, Mary Smith, Cheylynn Bosley-Somogyi, Annjanette Stone, and Jennifer Sporleder.