

Hybrid Alternative Driving Systems: Finding the Evidence to Improve Alternative Driving Control Outcomes

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Evidence based practice (EBP) is the integration of the best research evidence with clinical expertise & patient values to make clinical decisions.¹ The RESNA Wheelchair Service Provision Guide emphasizes the need to use EBP to identify the best practices, processes, and technologies that will lead to optimal outcomes. It stresses the importance of using peer reviewed research to guide clinical decision-making and the use of outcome measures to evaluate the effectiveness of the equipment, technology, and services we provide.²

No one should dispute that we need to adopt an evidenced based approach to providing complex rehab technology (CRT). At the same time, we must recognize that two of the most important factors in a successful CRT outcome are the *product* and the *specific configuration* used to provide the product. I refer to the process of determining which product and configuration are the best match for a given user's needs as a reasonably objective product analysis. The types of expertise that are required to perform that analysis appear in Figure 1.

Figure 1



Product-related expertise must be accounted for in any model used to provide CRT. A good working definition for evidence based CRT might be the integration of best research, clinical expertise, user preferences, and the information obtained from a reasonably objective product analysis to ensure that the best product is provided in the most-effective configuration for the needs of the individual user.

While products and configurations hold the key to many successful CRT outcomes, they are difficult to operationalize as variables for empirical study. Furthermore, it doesn't have an unlimited shelf life. Whenever products change or new technologies emerge we must also press the reset button.

This is especially true for adult end users with spinal cord injuries (SCI), multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS) who use alternative driving

controls. While their numbers may be small, they we be highly dependent on this technology for their everyday function. With so much at stake, we have an obligation to make the most informed decisions possible based on the best available evidence.

When we take an honest look at the status quo surrounding these products, however, not only will we find there is no peer reviewed evidence to support their effectiveness, we will find there is no real consensus about how to provide them. What's worse, the status quo has not changed significantly since I provided my first head array to a veteran with high tetraplegia back in 2005. Unless we change the status quo, and do so quickly, I'm concerned we may not see these products in the years to come.

Why hasn't the status quo changed?

A status quo will tend to be maintained when decisions take place in relative isolation using unproven assumptions, marketing information, or conventional wisdom. Changing the status quo requires us to rely on assessment more than assumption, realize that significant needs exist that are not being met, and we come to a collective realization that we need to change our approach.

Evidence based practice and continuous product improvement are similar concepts used in health care and manufacturing to improve the quality, efficiency, and effectiveness of products and services. Both concepts attempt to introduce change in a systematic way and ensure it will have a positive effect on the status quo. While we have had some success applying these concepts to products like custom ultralight wheelchairs, we have had little success applying them to alternative controls.

To understand why this has been the case, we need to make a couple of distinctions and consider the history of these products. First, alternative controls are produced in limited volumes. Very few of us provide them as part of our routine day. Second, there really is no "typical" end user of an alternative driving control. They are prescribed for users of different ages who may have any number of diagnoses--each of which has unique implications for the user's function and clinical needs.

Limited numbers and high heterogeneity practically guarantee that no manufacturer, clinician, or supplier will have a complete understanding of every need these products need to address or how effectively every product/configuration works with every population.

There are also four characteristics about these products that have inhibited any impetus for change.

1. Clinicians are usually able to obtain a detailed understanding of their client's needs, but few will have the firsthand experience they need with specific products to make informed decisions about the best product/configuration to meet those needs.

2. Alternative controls were developed for one purpose--to allow users who could not use a joystick to drive a powerchair. As a result, they do not address specific clinical needs and do not always work effectively in every routine context of use.

3. Most products continue to be sold in the same standard configurations and use many of the same components they have used for years. While the technology may have improved, their basic designs haven't evolved to take advantage of the added potential.

4. The current bar to effectively implement the technology in these products exceeds what is reasonable to expect of clinicians and suppliers in the field. As importantly, the ability to change the configuration to implement the technology in a different way can be equally difficult.

We will not see meaningful change in the status quo until these barriers are addressed.

Ideally, manufacturers could address these issues by incorporating user-centered design into the development of their products. Key concepts inherent to user-centered design (aka human-centered design) are the active involvement of users, input from multiple disciplines, and an iteration of design solutions.³ User centered design focuses on the user's needs and requirements and applies human factors/ergonomic principles to the development of interactive systems.⁴

We would be well advised to adopt the principles of user-centered design, evidence based practice, and continuous product improvement with these products. Because they are so intertwined, however, it would be extremely difficult for a clinician, supplier, or manufacturer to succeed on their own. We cannot remain strictly in our lanes and expect that checking a box on an order form or designing a new part in a CAD program will give us the result that we want. Success will require an "open" collaborative effort where everyone stays engaged, everyone's expertise is used, and everyone contributes.

I'm confident that clinicians can sustain the momentum needed for evidence based practice and continuous improvement, but only if manufacturers provide some inertia by making it easier to implement the technology in their products. The easier it is for individual clinicians to use, configure, and reconfigure alternative controls, the more accurately they can appraise their effectiveness in the populations they see. In turn, the more manufacturers realize they should use their marketing function as a way to engage clinicians to get their feedback, the more data they will have to make their products more clinically effective.

Many people may think that I've just described a dire situation for which I've proposed an overly-idealistic solution that would never work in the "real world". I would argue that given our real-world constraints, quite the opposite is true. I also wouldn't have gone to such lengths to describe the status quo without having tangible "evidence" that changes are, in fact, possible. I refer to the application of open development and open innovation to complex rehab as "Open CRT" and believe it is the best way to improve

the effectiveness of complex rehab products and services in a way that will have a demonstrable impact on CRT outcomes.^{5, 6, 7}

Configurations of products that reflect this approach will be on display in the exhibit hall and will be used by participants during the session for which this paper was written. Clinicians who may have never used an alternative control configured for complex needs will have the opportunity to acquire firsthand experience of what is possible when the technology is easy to implement and adaptable configurations are used.

Both powerchairs will be equipped with Hybrid Alternative Driving Systems (HADS). HADS combine characteristics of more than one type of alternative driving system to enable key functions to be assigned to other points of control. They can be effective when an end user lacks sufficient head control, oral motor function, passive range of motion, voluntary movement, or cognitive function to use any single type of system.

The products that will be used come from competing manufacturers who listened to constructive feedback about how effectively their products were meeting the clinical needs of a specific population. Some of the innovations originated in the clinic while others were developed by the manufacturer. They were all developed to address specific needs that were identified during service delivery and were refined through an iterative process. Some have been incorporated into production while others are now available as custom configuration requests. They embody what is possible when clinicians collaborate with manufacturers toward mutually shared objectives.



Permobil F3 ALS Assessment Powerchair



Quantum Q6 Edge 2 ALS "Concept Chair"

How did they make it to Nashville?

It all started by observing, assessing, identifying, and trying to understand why specific groups of users had difficulty using power mobility in one clinical setting.

The road to evidence based practice will be paved with practice based evidence

It is unrealistic to expect that one day we will open up a peer reviewed journal and find a landmark study published about the effectiveness of specific alternative controls in the specific user populations that we work with. While not a substitute for evidence based practice, Practice Based Evidence (PBE) offers an alternative for clinicians when EBP is unlikely to provide convincing or consistent empirical evidence to support or refute a practice.^{8,9}

Every time a clinician critically assesses for themselves how effectively a given product provided in a specific configuration meets the needs of its intended user, they can accrue practice based evidence to guide future decisions. If clinicians are consistent and systematic in their approach, it is possible to analyze data collected from their own practice to identify issues that tend to exist in specific groups of users. Once issues are identified, it becomes possible to address them proactively in the clinical services and product configurations we provide. In some cases, practice based evidence will result in innovation, or "practice based solutions", that may be of benefit to similar users who are followed in other clinical settings.

We will never see evidence based practice with alternative controls unless we share practice based evidence with our peers.

Practice based evidence can lay the foundation for an evidence based approach to custom mobility equipment provision, but only if it is shared in a responsible, objective, and clinically-qualified manner. Whenever we identify a recurrent issue or develop an effective solution, we have an obligation to share it with others. Not only might our findings help others attain better outcomes, we create opportunities for others to validate our findings, build upon them, or suggest alternatives. Unless we take that additional step, we can never know for certain whether something may be common sense, common knowledge, or a common problem.

Practice based solutions that have the potential to benefit a significant number of users should be shared with manufacturers. In many cases, they can be made available to all as custom configuration options. In some instances, they may be incorporated into standard product as part of continuous product improvement.

PBE Finding 1: Proximity Head Arrays may be ineffective in some adult populations

To illustrate the potential value of sharing practice based evidence, I would like to share my experience providing proximity head arrays to veterans between the ages of 20-80 years who had extensive paralysis due to SCI, MS, or ALS:

Since 2008, fewer than 5 veterans followed by the SCI/D Service at the Cleveland VA have successfully used a proximity head array in the manufacturer's standard configuration to independently drive the powerchair and fully tilt the seating system without a need to make significant modifications.

While this may be anecdotal information, it reflects the experience providing these products at one of the VA's 24 Regional SCI/D Centers and an ALS Certified Center of Excellence. It may lack the scientific rigor to be published in a peer reviewed journal, but it is still clinical evidence that has significance that should not be completely dismissed.

Having shared that experience, consider how much more could we know about the effectiveness of these products in this population if clinicians from just one similar setting also shared their experience?

Whatever the outcome, simply sharing those findings could change the status quo.

PBE Finding 2: A true Sip-n-Puff system should be ruled out before pursuing other switch based alternative control options in these populations

In my setting of practice, the closest thing to a stereotypic end user of an alternative control would be a newly injured user with C4 tetraplegia who has no other functional impairments. For these individuals, there is very good possibility they will be able to use a four-function pneumatic switch to efficiently drive and tilt their seating system. This is

the only alternative control that I've found will reliably allow these users to meet my minimum criteria for a successful outcome--driving and fully tilting the seating system.

Why does it work?

- It provides reliable access to four switch inputs without using head movements.
- Switch access doesn't change when power seating is used.
- It does not require precise positioning in the chair and will accommodate minor variations in positioning.
- Latched driving reduces the need to use sustained control inputs.

When doesn't it work?

- Oral motor dysfunction exists to an extent where precise regulation of intra-oral pressure is not possible.
- Cognitive dysfunction.

What doesn't matter?

- Respiratory insufficiency.
- Tracheostomy/Ventilator dependence.

Once a true sip-n-puff has been ruled out, all bets are off as to whether the user will be able to achieve the same level of proficiency and a much greater investment of time and resources will be required to achieve a similar result.

For this reason, the four-function pneumatic switch should be ruled out before other switch based alternative controls are pursued.

In my clinical setting, a significant number of the veteran's I see are unable to use a four-function pneumatic switch. Many of these users have ALS and will have very limited options if only standard configurations of existing products are considered.

The question becomes where to go next. Sometimes, we need to look to what others are doing to validate what we are seeing in our own setting.

PBE Finding 3: C4 Tetraplegia Case Study

Subject: Sam S. is a 52 year-old male with C4 tetraplegia secondary to an MVA in January of 2000.

History: For many years, he has used a conventionally configured 3 sensor proximity head array with a mechanical switch mounted on a lower swingaway rod for the reset/mode function.

In 2014, he trialed another wheeled mobility device equipped with an experimental driving system that used infrared cameras instead of lateral proximity sensors to steer

using lateral cervical flexion. A sensor embedded in the headrest and configured for step latched activation was used for acceleration using cervical extension. To eliminate the need to come to a complete stop when needing to slow down (as is the case with most 3 sensor head arrays), a novel bite sensor was developed to serve as a "brake".

Results: On a standardized course, the subject was able to attain a maximum speed of 97 mph over four attempts.

In 2016, he trialed a second generation of this system. The headrest sensor and bite sensor were replaced with a 2-way pressure sensor (similar to a 2-function pneumatic switch). The infrared camera system was reconfigured to register cervical rotation instead of lateral flexion for steering.

Results: On the same standardized course, the subject attain a maximum speed of 152 mph--an improvement of 55 mph.

Conclusion: The use of cervical rotation for steering combined with simple sip-n-puff input for acceleration/braking resulted in a 57% improvement in top speed on a standardized course. While the change in velocity of 80.67 feet per second was deemed statistically significant, caution should be used when applying these results to current products on complex rehab powerchairs.

For those who haven't guessed, the standardized course happens to be The Indianapolis Motor Speedway and the subject is former Indy car driver, current team owner, and C4 tetraplegic, Sam Schmidt. The wheeled mobility device is a modified Corvette known as the Semi Automatous Motorcar (SAM)--an open innovation project led by Arrow Electronics to demonstrate the potential applications of off-the-shelf-technology.^{10, 11}



Former Indy car driver and C4 tetraplegic Sam Schmidt behind the wheel of the Arrow Electronics Semi-Autonomous Motor Car (SAM 2.0). Reflective markers on his glasses are tracked by infrared cameras inside the car to allow him to steer using cervical rotation. A Freescale pressure sensor (similar to a two-function pneumatic switch) is used for acceleration and braking. Photo courtesy of Arrow Electronics.

What does this have to do with Alternative Controls?

In the span of only two years, one very knowledgeable end user and a few engineers from a handful of tech companies realized that changing two things would improve the SAM's ergonomics to improve performance.

- 1) Allowing the headrest to provide a source of stability and using cervical rotation to steer is more efficient than using the headrest as a source of input and steering with lateral flexion.
- 2) Using intra-oral pressure to control acceleration & braking combines two inputs into one point of control that does not require active movement.

These same things would also improve the ergonomics of using a head array. How did they accomplish something in two years that we haven't realized for over a decade?

- No status quo existed for this project--just a shared outcome they wanted to achieve.
- They focused on the task at hand, observed, assessed, changed, and reassessed.
- When they identified issues with the original configuration, they had the ability to implement the technology in a different way to improve efficiency.

That last point has really held us back.

Adaptability: If at first, we don't succeed, products need to allow us to try, and try again

Successful complex rehab outcomes require an accurate understanding of the user's function, clinical needs, specific products, and effective configurations. For users with SCI, MS, and ALS, the product and its configuration may be the *only* variables that can be changed to effect an outcome. We cannot continue to treat them like they are the "control variables". That's exactly what we do when we mount 3 proximity sensors and a mode switch in fixed locations using hardware that cannot be adjusted without tools.

We need think of the product's configuration as the experimental variable in our outcome that we are able to change the most. Unlike the static configuration of a conventional head arrays, a HADS configuration is designed with change in mind. They allow us to precisely position the right type of sensor/switch in the optimal location and assign it the best function for the user's abilities.

The characteristics of a product that allow it to be easily reconfigured to meet the user's needs is something I call *adaptability*.

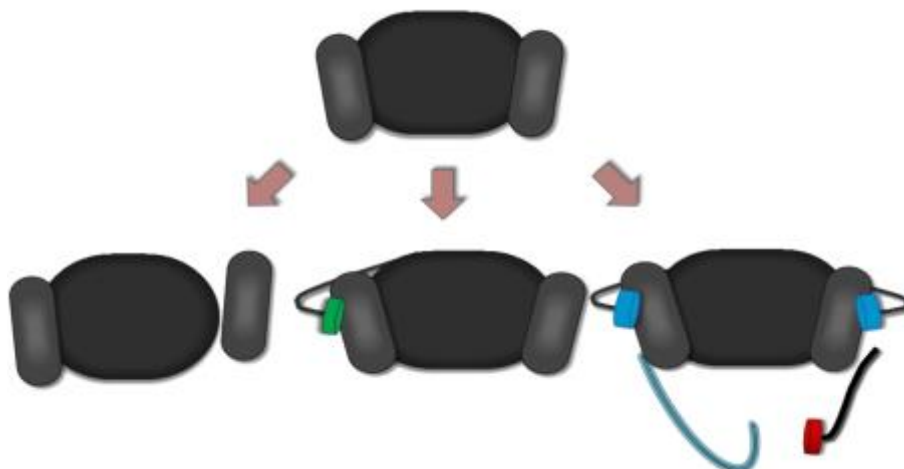
While today's alternative controls are generally *adjustable*, few are truly *adaptable*. This is an important distinction to make since providing today's products in something other than the manufacturer's standard configuration is a significant barrier to optimizing clinical outcomes. Products need to do more than just adjust to the user, they need to *adapt* to meet their individual needs.

Many of the users I see have clinical issues *besides their paralysis* that will adversely affect their ability to use alternative controls. To attain an optimal outcome, these users require highly individualized configurations that take full advantage of any useable function they have. It is only possible to optimize these configurations if it is possible to use an iterative approach when providing them. A significant number of the adults I see have progressive conditions. Their needs are best addressed by products that can be reconfigured to meet changing needs with minimal disruptions and delays. Adaptability is needed to make these things possible.

To provide adaptability in an alternative control, designs should provide a basic infrastructure that supports switch access, a flexible interface, interchangeability, and modularity. Adaptable configurations allow us to easily add new components, substitute them, and assign/reassign functions to the best point of control for the user's abilities. They also allow us to address clinical needs by applying the clinical principles that would be used to address the problem in other contexts.

Headrests that provide comfort, headrests that provide positioning, and head arrays are traditionally thought of as distinctly different products. However, a significant number of users would benefit from characteristics of all three. I've started to base Hybrid Alternative Driving Systems on a modular headrest that provides comfort, reliable switch access, and sufficient positioning and stability to address mild asymmetry and support the movements used to activate a sensor or switch.

Figure 2



"Position & Place" Modular Headrest. A 6"x4" occipital pad combined with two vertically oriented 4"x2" spot pads provides roughly the same surface area as a 10" headrest, but can address asymmetry and support the movements used for switch activation.

The Concept of "Position & Place"

We need to accept the reality that very few users consistently sit the same way. Even when they do, the orientation of their head relative to their body and their fore/aft location in the seat are likely to change by inches when they tilt their seating system to reposition, redistribute pressure, or counter postural rounding. These are important contexts of use that may be as important as driving the powerchair.

Individuals who need these types of products require switch mounting solutions that provide enough rigidity for efficient activation with a limited amount of precise adjustability for accurate placement.

Combining a source of proximal support with the ability to precisely position the switch/sensor within the range that allows it to be activated using cervical rotation (i.e. "rotation with stabilization") is critical to provide to using a head activated system efficiently for many users. This can be especially difficult to achieve when the seating system is tilted.

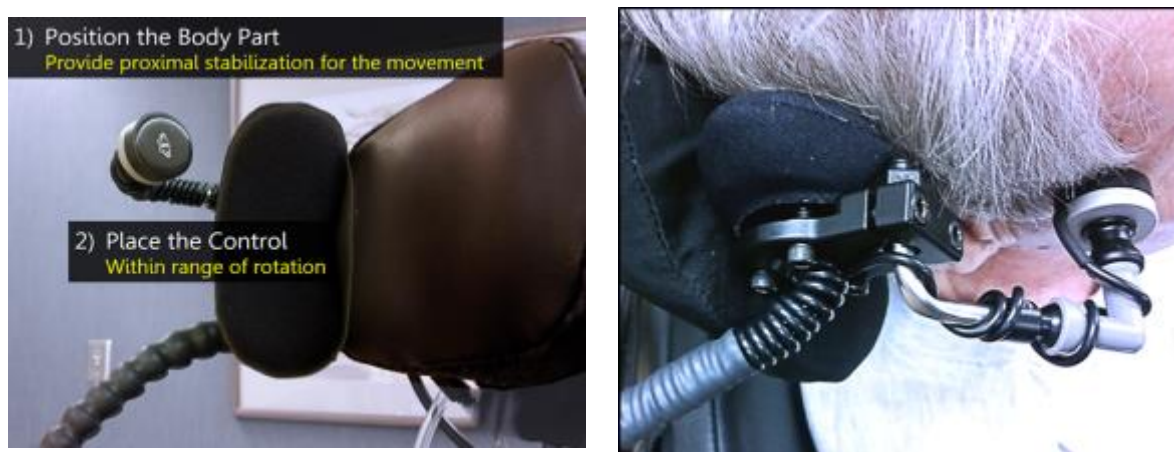
The 1/4" stainless steel precision adjustable switch mounts shown in Figures 3 & 4 represent a particularly significant practice based solution to come out of my clinic during the past year.

Figure 3



A significant "practice based solution" are these precision adjustable switch mounts fabricated out of 1/4" stainless steel tubing, modular hose, a CNC ball socket adapter, and a flattened Loc-Line end cap. The picture on the right shows these mounts on the "Position & Place" modular headrest.

Figure 4



"Position & Place" is the ability to position a driving control, sensor, or switch precisely where the user needs it with sufficient proximal support for the movement. For head activated switches/sensors, the goal is to enable rotation through proximal stabilization.

The most critical part of a complex configuration is something we can't not see

If manufacturers can "lower the bar" required to implement their technology, we can raise the bar with respect to the outcomes we can expect. I know from what I've learned since I developed these solutions that the learning curve is greatly accelerated when the technology is easy to implement.

All four of the following HADS configurations have been used successfully by veterans followed by our service. All use a nearly identical programming profile.



All four systems are configured as *four axis step latched systems*. Four axis step latched driving requires 5 switch inputs (a separate mode switch is required), but is an ideal configuration for many users because it requires only brief inputs to drive and the reverse command can be used to slow down. The incremental nature of a stepped latch configuration is also easier to learn because the user can see the results of each input. 3 axis stepped latch configurations eliminate the need for a mode switch, but require the user to stop instead of slowing down and toggle between forward/reverse.

Three of the four configurations also use a 2-function pneumatic switch (2 for direction, 1 for steering). Unlike the 4-function pneumatic switch used in a true sip-n-puff system, a 2-function pneumatic switch does not *require precise regulation of intraoral pressure*. Provided that sustained inputs are not required (e.g. momentary input or used for steering) most users, *including those with ALS*, can use this type of switch. I have had users with significant dysarthria and sialorrhea use one successfully. Because it provides two inputs from a single location that is not affected significantly when the seating system is tilted, it should be ruled out before exploring alternatives. For this reason, the majority of the HADS configurations I have provided include a 2-function pneumatic switch. ^{12, 13}

Even users who have the ability to use a conventionally configured head array, will benefit from this switch because it allows a head array to be configured for 4 axis step latched operation. It is a disservice for users who exhibit the level of function required

to use this type of system to have to stop when all they want to do is slow down or feel they are having to wait an eternity to "stop & toggle" in a public place or maneuver their chair in a vehicle so it can be secured in place.

Conclusion

I doubt many clinicians who read that last paragraph would not want their clients who use alternative driving controls to be able to seamlessly slow down and not "stop & toggle". At the same time, there are a significant amount of users who receive conventional 3 axis head arrays without first ruling out a 4-function pneumatic switch or a sip-n-puff head array. While a good deal of this paper addressed issues with current products, as clinicians we have a lot work to do before we will see evidence based practices for providing these products. The first step is to learn how they actually work.

There is a path to an evidence based approach, but we must recognize that it will be built one user at a time, through an open approach, where everyone plays a role. We will not succeed on our own.

Please feel free to share.

References

1. Arledge, S., Armstrong, W., Babinec, M., Dicianno, B.E., Digiovine, C., Dyson-Hudson, T., Pederson, J., Piriano, J., Plummer, T., Rosen, L., Schmeler, M., Shea, M. & Stogner, J. (2011). The RESNA Wheelchair Service Provision Guide. Arlington, VA: RESNA2011. Retrieved from: <http://files.eric.ed.gov/fulltext/ED534426.pdf>. ERIC Number: ED534426
2. Sackett, D.L., Richardson, W.S., Rosenberg, W.M., & Haynes, R.B. (1997) Evidence-based medicine: How to practice & teach EBM. New York: Churchill Livingstone.
3. Ergonomics of human-system interaction—Part 210: Human-centered design for interactive systems (2010). Geneva: International Standards Organization. Retrieved January 9, 2017, from http://www.iso.org/iso/catalogue_detail.htm?csnumber=52075
4. User-Centered Design Basics. (n.d.). Retrieved January 9, 2017, from <https://www.usability.gov/what-and-why/user-centered-design.html>
5. Mitchell, S. J. (2016). Making The Argument For "Open CRT". Mobility Management. Retrieved January 9, 2017, from <https://mobilitymgmt.com/articles/2016/05/01/open-crt.aspx>
6. Mitchell, S. J. (2016). Open CRT: Everyone's Responsible. Mobility Management. Retrieved January 9, 2017, from <https://mobilitymgmt.com/articles/2016/06/01/open-crt.aspx>
7. Mitchell, S. J. (2016). Open CRT for ALS: A Demonstration. Mobility Management. Retrieved January 9, 2017, from <https://mobilitymgmt.com/Articles/2016/08/01/CRT-for-ALS.aspx>
8. Horn, S. D., & Gassaway, J. (2007). Practice-Based Evidence Study Design for Comparative Effectiveness Research. Medical Care, 45(Suppl 2). doi:10.1097/mlr.0b013e318070c07b
9. Practice-Based Evidence Applied to Adult, Medical Speech-Language Pathology. Perspectives on Gerontology, 18(1), 14. doi:10.1044/gero18.1.14
10. Sam Schmidt, quadriplegic former racer, drives again at Indy Motor Speedway. (2014, May 18). New York Daily News. Retrieved January 9, 2017, from <http://www.nydailynews.com/sports/more-sports/schmidt-quadruplegic-ex-racer-drives-indy-article-1.1797313>
11. Arrow Electronics. (2016, May 22). Arrow Electronics' Semi-Autonomous Car Hits Record 152 MPH With Quadriplegic Former Racecar Driver Behind the Wheel [Press release]. Retrieved January 9, 2017, from

<http://www.businesswire.com/news/home/20160522005045/en/Arrow-Electronics%E2%80%99-Semi-Autonomous-Car-Hits-Record-152>

12. Mitchell, S. J. (2016). ALS & Headrests: How Open CRT Offers New Opportunities. Mobility Management. Retrieved January 9, 2017, from <https://mobilitymgmt.com/Articles/2016/09/01/ALS-Headrests.aspx>.

13. Mitchell, S. J. (2016). Open CRT & ALS: From Snowflakes to Ice Cubes. Mobility Management. Retrieved January 9, 2017, from <https://mobilitymgmt.com/Articles/2016/10/01/Open-CRT-ALS.aspx>.