

# Multi-disciplinary and lean innovation for AT

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**Abstract:** Upper limbs are not suitable to provide mobility for a long time. Pushing a manual wheelchair is inefficient and might cause serious upper body overloading. Long-term wheelchair pushing almost inevitably leads to steadily deteriorating physical capabilities for the user. The World Health Organization (WHO) estimated that at least 1% of the world's population uses a wheelchair. Novel multidisciplinary teams and processes, working with lean innovation and validated learning approaches are the key to design, develop and provide new categories of assistive technologies that can further improve the health, quality of life, and autonomy of this large number of people by addressing important unmet needs.

## Introduction and objectives

The "Active Powered Wheelchair" (APW) could represent a new category of assistive technology that provides an improved level of mobility and independence for people with disabilities and might serve as a physical rehabilitative medical device that indicatively can contribute to protect, maintain, and improve bodily function. It is not propelled forward or backward by the use of a person's hands or arms, but rather by an electrical motor that responds to shifting weight on the seat through subtle upper torso movements that may provide training in the form of additional physical therapy. It is designed to remove the negative health impacts affecting active wheelchair users caused by the wear and tear on fingers, hands, wrists, arms, and shoulders necessary for manual wheelchair pushing. The APW requires the ability to self-balance the wheelchair through control and coordination of movements of the upper body and the head. The subtle movements back and forth of the upper body allow mobility without the use of the upper limbs, leaving hands free to steer the wheelchair or to perform tasks or work activities while in motion that were previously not possible with an active or power wheelchair.

The APW's use of the innovative technology of "Self-Balancing Advanced Mobility Systems" opens the door to a "fourth industrial revolution" in the design and production process of

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wheelchairs as we know them today, and the technology is cited as an example for such progress in this manuscript.

## **Background**

The wheelchair was conceived as a mobility device to enhance the ability of people with limited walking abilities to be able to be more independent, attend school, work, and participate in social activities. Over the centuries, R&D, design improvements, and more efficient manufacturing techniques, have led to lighter products, construction with carbon fiber instead of iron or wood, models that were easier to push or self-propel, the ability to lift, fold or disassemble a wheelchair with one hand, among others.

### **The limits of active wheelchairs: Pushing is not natural or efficient, and can cause health deterioration**

While the manual (active) wheelchair has allowed people with disabilities greater mobility, it still uses the same basic technology invented almost 90 years ago by Harry Jennings and Herbert Everest that requires the use of the human body as a propulsion system. Time has shown that its long-term use could undermine people's health, which would be counter-productive to the reason for its existence. In fact, the WHO's Global Cooperation on Assistive Technology (GATE) definition of an assistive product is a device "... whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing"[1].

Homo sapiens upper limbs are not suitable to provide mobility for a long time[2]. Pushing a manual wheelchair is inefficient and it might cause serious upper body overloading[2]. Long-term wheelchair pushing almost inevitably leads to steadily deteriorating physical capabilities for the user[2]. Rotator cuff tears were present in 49%, unilateral in 20% and bilateral in 29%[3]. Additionally, about half of the people who use an active wheelchair eventually develop carpal tunnel syndrome[4]. Moreover, the most common posture acquired while using an active wheelchair, thoracic hyperkyphosis, was associated with a markedly high rate of rotator cuff tears[5]. The repetitive strain imposed on the upper body - hands, fingers, wrists, elbows, and shoulders - by pushrim propulsion leads to a very high prevalence of additional medical care in active wheelchair users[2].

Avoiding the damage from long-term use of an active wheelchair can require a shift to a power wheelchair, even for people without severe medullary lesions. Compared to an active wheelchair, a power wheelchair is less physically demanding, and can lead to a more sedentary lifestyle and lack of use of active muscles that can result in additional secondary health problems and an increased need for medical care. Moreover, because the power wheelchair was developed for people with tetraplegia, and people with injuries that severely restrict bodily movements, patients with less severe injuries such as paraplegia often do not feel comfortable using it because psychologically the transition to a power wheelchair

sometimes creates a deep downgrade in self-esteem[6]. For some people a power wheelchair may not be feasible due to financial constraints or difficulty transferring, or transporting it.

Usually, rehabilitative and preventive measures to mitigate the effect of using an active wheelchair are performed together with injury-specific clinical practices. Occupational and physical therapists teach users which specific muscles need to be stretched and strengthened to protect the structures of upper limbs, provide stability, improve transfer and wheelchair propulsion skills, and prevent other secondary health conditions (SHCs). Neuropathic pain (83.7–92.1%), musculoskeletal pain (62.3–87.1%) and urinary tract infection (56.5–58.9%) were the most frequently reported SHCs[7]. Additionally, active wheelchair-related accidents can occur during transfers, propelling over uneven terrain, reaching for objects, and maneuvering curbs or stairs. Tipping and falling are the most common form of incidents[8].

Therefore, despite the positive innovation in conceiving, designing, and producing active wheelchairs, their long-term use is, still today, a critical health issue[9]. The objective of the active power wheelchair is to address these shortcomings and fulfill unmet needs by providing a practical and effective assistive technology that improves not only a person's autonomy, but also serves as a physical rehabilitation medical device to improve their health and wellbeing, which is in line with a "WHO Factsheet on Wheelchairs"[10] that says that "wheelchairs should be designed to enable users to lead a more active life and to participate in as many activities as possible without affecting their health and safety.."

### **Methodology for a multidisciplinary assistive technology innovation process**

With the goal of identifying the main critical issues for long-term active wheelchair users, and to propose both a process and technologies for addressing them, we performed grey literature searches within Google Scholar, WHO, UN and other sources, in addition to specific academic searches on PubMed, Disability and Rehabilitation: Assistive Technology Journal, Disability and Rehabilitation Journal, and the Journal of Product Innovation Management. We used as a timeframe the last 16 years of publications in English, and we included reviews, pilot studies, cross-sectional studies, case studies, factsheets. We used the following keywords: postural abnormalities, wheelchair, active wheelchair, rotator cuff tears, long-term, secondary health conditions, shoulder surgery, SCI rehabilitation, lean innovation, product innovation, innovation management.

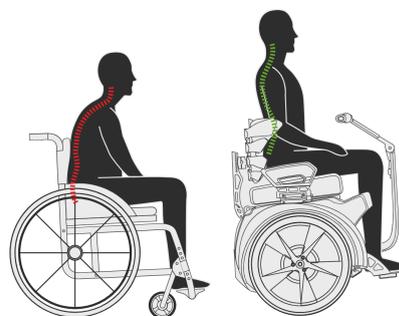
### **Active Powered Wheelchairs and the positive health effects of self-balancing motion schemes**

The recent emergence of active powered wheelchairs based on self-balancing technology is particularly interesting because it reproduces the same motion as walking but the propulsion comes from an electric motor stimulated by subtle movements of a person's

upper body, shifting weight on the seat. That means that with Self-Balancing Advanced Mobility Systems the human body generates the motion in a different way. Moving the APW forward requires tilting the torso forward, and stopping the wheelchair requires moving the torso backward. The active power wheelchair has only two wheels, eliminating the front casters, and is both active (uses the body) and power (uses the electric motor) at the same time.

A self-balancing APW is not suitable for all forms of motion disability. Medical guidelines must be developed and required to assess and define each case individually. People need to satisfy several clinical prerequisites. They need to have good control and functioning of the upper limbs; good control and coordination of movements of the head and of the torso in forward and backward positions, even with a non-stabilized spine. They must be able to transfer (on and off) the wheelchair independently, and maintain their balance in the sitting position. In a broader sense, the self-balancing wheelchair can be used, for example, by anyone with paraplegia, incomplete tetraplegia that meets specific requirements, people with neurodegenerative diseases in the initial stage, people with lower-limb amputations, and those with illnesses such as poliomyelitis, cardiovascular diseases, or other fatiguing conditions.

To operate the active power wheelchair requires movements equivalent to physical exercise that have a wide range of positive effects on the user's health. Sitting in the right position to properly activate the mobility response allows users to avoid posterior pelvic tilt, kyphotic spine, and any other incorrect posture-related conditions. The joints of the fingers, wrist, elbow, and shoulders are hence protected, as they are not used to propel the wheelchair. Moreover, using self-balancing technology brings added value to the neurorehabilitation of the person's equilibrium because it requires continuous control over the body, activation of the location senses, movement back and forth, and self-balancing while remaining stationary. Propelling the wheelchair forward and backward requires exercising postural control. The presence of an electric motor enables long-distance autonomy and the possibility to travel uphill and on uneven outdoor paths impossible to access with an active wheelchair. This expanded freedom creates a positive impact on a person's self-esteem through the psychological perception of a more friendly and accessible social environment in which the person can finally be more autonomous.



## Posture and equilibrium control on active vs active powered wheelchair

For the first time, the active power wheelchair demonstrates how mobility and rehabilitation features can coexist in the same assistive technology product. Physical rehabilitation protocols could now include exercising that occurs naturally by using the active power wheelchair for daily mobility activities. This can reduce the cost and number of physical rehabilitation visits, as well as produce savings due to the avoidance of damage to fingers, hands, wrists, elbows, and shoulders, as well as secondary health conditions such as neuropathic pain.

The Self-Balancing Advanced Mobility Systems constitutes a new propulsion system for active wheelchairs. Currently, self-balancing wheelchairs are under ISO 9999:2016 in 12 class 23 subclass and 06 division, so that as powered wheelchairs if we only consider the propulsion system. Taking into consideration the role of the human body, this could create the need for refining the AP classification category as "Active Power Wheelchairs (APW)"..



Active Wheelchair (AW)



Power Wheelchair (PW)



Active Power Wheelchair (APW)

### **An "Active Powered Wheelchair" (APW) as a new category of 21<sup>st</sup> century assistive technology that is both mobility and rehabilitative medical device**

An innovative APW goes beyond the concept of mobility and integrates elements of physical rehabilitation into its design and function. Although an APW may initially be manufactured in high-end user countries, through technology transfer it can become available to people living in low-resource settings. To achieve this there must be international standards and regulatory frameworks for this new technology that ensure its effectiveness, high-quality and safety. Currently, there are companies manufacturing active power wheelchairs in the absence of such regulations and this could result in wheelchairs that are dangerous and unsafe. This paper invites manufacturers worldwide to come together and work in synergy to leverage the full potential of this innovative process for the benefit of people with disabilities around the world, 85% of which live in developing countries. In several Southeast Asian countries, scooters and e-scooters are more prevalent than in high-income countries because they are inexpensive to own and easy to use. Therefore, it may be possible with government or international financial assistance to expand existing infrastructures to

produce APWs. Since adopting new innovative technologies takes time, in the interim there are projects like FreeWheel[11], funded by the European Commission, that are developing a low-cost self-balancing electrical module that can be attached to a manual wheelchair to propel it forward and relieve people across the globe from the health damages and fatigue caused by manual wheelchair pushing.

### **Preliminary results from two pilot studies on the APW**

In addition to regulatory standards, medical guidelines and patient assessment criteria for APWs, there also need to be more clinical trials to provide scientific evidence of the health benefits they can provide. There are very early preliminary results from two pilot university studies on APWs. The first study is entitled "Occupational therapy in the assessment of the self-balancing wheelchair rehabilitation value in the post-acute phase of people with medullary lesion: pilot study"[12] done by the Università Cattolica del Sacro Cuore - Faculty of Medicine and Surgery "A. Gemelli" in Rome and experiences within the Unipolar Spinal Unit "Niguarda Ca 'Granda Hospital" in Milan. The study collected the data of the 8 patients with spinal cord injury who own an APW, to verify for the first time whether it also has a valid rehabilitative value in terms of the balance of the trunk, influence on spasticity, influence on the pain of the limbs, upper limbs and spine, influence on performance in the "activities of daily living" (ADL). The evaluation protocols used in the study are: Shoulder Pain and Disability Index (SPADI); Wheelchair User's Shoulder Pain Index (WUSPI); Visual Analogic Scale (VAS); Modified Ashworth Scale (MAS); Penn Spasm Frequency Scale (PSFS); Spinal Cord Assessment Tool for Spastic Reflexes (SCATS); Sitting Balance Scale (SBS); Spinal Cord Independence Measure (SCIM); and SF-36 (VI) standard health questionnaire. The main results suggest that the APW reduces shoulder pain due to its special ability to move without the person using their arms to push. The patients recorded reduced pain between 4% and 35%. Using the SBS scale, which measures the balancing ability of the trunk of the body, the study recorded that all patients had an appreciable improvement on average of 12.4%. The conclusion of the study is that the APW, due to its self-balancing property, greatly stimulates the body's ability to balance itself due to the constant exercise derived from daily movements using the wheelchair.

The second pilot study is "Use of The International Classification of Functioning, Disability and Health (ICF) in the assessment of a self-balancing advanced mobility system"[13] within Alma Mater Studiorum, University of Bologna. This study employed a method of assessing the general health of an individual, using an advanced self-balancing mobility system such as an APW. To achieve the study goal it was necessary to select the most relevant ICF checklist items related to physical rehabilitation and social inclusion, which are the areas in which mobility assistive technologies are used. The results of the customized checklist show significant improvements in the performance of activities and social inclusion, mainly related to the relationship with others, such as relatives and friends, as well as leisure activities.

Through the pilot studies, it was possible to obtain an early evaluation of both health and economic benefits deriving from the daily use of an APW, which lays the foundation for the continuation of more specific and in-depth studies on these issues.

### **Multidisciplinary, lean innovation, and validated learning processes for APWs**

Developing the Active Powered Wheelchair implies a change in the perspective of building an assistive technology with a focus not only on maximizing mobility and autonomy and avoiding secondary health conditions but also on incorporating effective physical rehabilitation into the everyday use of the wheelchair. The innovation process requires new skills that were previously not conceived of, or included as critical, in the product design and innovation process of an active wheelchair. For example, physiotherapists and occupational therapists should now play an important role during the "discovery of needs" and the "evaluation process", to catalyze the rehabilitative data analysis.

To be successful, a multidisciplinary innovation process must deliver three things: superior solutions, lower risks, and change-related costs, and employee buy-in. The entire multidisciplinary process is governed by a balanced mix of what are called "Scrum" and "Lean" approaches. While "Scrum" provides the iterative structure to the team, "Lean" innovation principles require human empathy, as well as end-user experiments and evidence that reduce waste in the design phase - technically combining three essential methodologies: design thinking, and the ability to remain lean as well as agile.

A "lean innovation process" uses "validated learning" as the main practice to assess and develop the right assistive technology, in this case, an APW. The "validated learning process" includes a multidisciplinary team composed of electrical, mechatronics and software engineers; product designers; physiotherapists and occupational therapists; user researchers; public policy and legal regulations specialists. It brings together all stakeholders who have a shared interest in the success of the APW's final outcome. "Validated learning" employs a process in which the team translates an assumption into a hypothesis, which it then tests with a series of studies, usually engaging real-world end-users of the assistive technology they are developing. The design and production teams then process the data collected from the studies and learns from it so that it feeds into the product design and development phases. Practices and experiences that focus on the end-user of assistive technology should allow the team to quickly adapt to new information and prioritize features important to the end-user, as well as make decisions based on market-based evidence. For example, preserving shoulder joints from wear, rehabilitating and improving bodily balance while in motion, adapting to changing health and muscle capabilities of the end-user, and providing increased autonomy and additional health and social benefits for the person using the wheelchair, are all challenges that new technologies must overcome.

Striking the right balance between all of the above-mentioned processes can be found in a modern and innovative approach named "Agile Customer Thinking", which can be described

as a continuous cycle of user response and action, a method of relentless technology improvement and customer co-creation[14]. For organizations and teams exploring brand new categories of assistive products, that is, devices that the customers or end-users have not yet "seen", it is necessary not only to explore the feasibility of the technology or the business viability but also to co-create the technology with the end-users. The end-users often do not know what they want until they see it[15], and one of the purposes of the "lean method" is to continuously learn from the feedback provided in the studies with them, to be able to adapt the APW to the needs of the individual user almost in real-time. Working towards solutions that the end-users both discover themselves and co-design provides true value[16]. It also establishes value metrics and ensures the design team has direct contact with the end-users who understand how their efforts and feedback are producing value[17]. This scenario creates an environment where the end-user becomes a partner in the product design process and where delivering valuable outcomes to them becomes the main focus for the team developing the product and its related services. "Agile Customer Thinking" offers the design and production teams - and the entire organization - a lean, agile design framework for operating in co-creation with end-users to develop, with low risk and high confidence, new assistive technologies that solve the users' unmet needs and promote technological progress[18]. In fact, the most effective modern organizations have re-engineered themselves as a network of autonomous, responsive small teams[19] with substantial innovative freedom and accountability[20].

Summarising, the advantages of using Agile Customer Thinking approach are related with (a) using data all the time so it's not a linear process with data at the beginning, (b) testing and measuring with real-time connected behavior, making an instant feedback loop that gives the organization needed insight before it becomes outdated; (c) using digital platforms that can allow teams to test and collect behavioral data at scale - at close to no additional cost; (d) continuous data collection through automated software; (e) sharing anonymized data openly with anyone on the team or in the organization, so that everyone is enabled to translate the insights into a solution through a democratic, inclusive model; (f) the need for continuous input that small teams are dependent upon to learn, evaluate and improve.

The traditional wheelchair provision with a linear flow, usually including the design, production, supply and delivery of wheelchair services, finally has an iterative circular flow with a closed feedback loop that includes the end-user.

### **Public policies, regulations, education, and training for a new category of assistive technology, the APW**

International and national public policies and regulations play a key role in product design for assistive technologies, especially new ones.

APWs are assistive technologies that do not yet have a proper commercial market or medical and industry regulations. Only some APWs are Class I medical devices and have self-declared medical guidelines. This lack of regulation is a matter of grave concern. To correct this situation, it is imperative that product innovation teams interact with policymakers in order to facilitate the development of new rules and regulations on APWs for the quality, design, safety, testing, and service delivery processes. Suppliers of assistive technologies should be required to officially register as such. The provision of APWs requires a medical prescription and the fulfillment of specific medical criteria, including the successful completion of a certified education and training course.

The WHO's GReAT Summit 2017 Report notes a balance that needs to be maintained between international or national product standards that can be experienced as a barrier to innovation and affordable production, and the need for a set of minimum standards to which assistive technologies are fit-for-purpose, of high quality, and safe. The report calls for "internationally-applicable, simple guidelines; minimum requirements; legal frameworks for provision; and AT information systems"[1]. The report proposes that "strategies could include building stakeholder networks based on existing models and the development of private and public partnerships"[1].

Therefore it is essential that public policy and legal regulation specialists are included in the multi-disciplinary team, lean innovation, and validated learning processes for APWs, as well as the Agile Customer Thinking cycle of feedback and action. They must also ensure adequate research funding, clinical trials to provide evidence of effectiveness and safety, and the dissemination of knowledge about new and innovative assistive technologies.

### **Affordable active powered wheelchairs for low-resources settings**

Advanced prototypes for APWs as Class I medical devices currently exist[21]. Because APWs are highly technological assistive devices, that have not yet reached the stage of mass production and economies of scale, they are expensive. Therefore, both technological innovation efforts and business models need to push towards cost reduction for the public health system and the end-users. Additional research is required as to the extent of time and cost savings APWs provide to national healthcare systems by enabling some physical rehabilitation to be done independently by the APW user, and by avoiding or eliminating secondary health conditions requiring medical care – savings which can offset APW production costs.

Luckily, the market already offers plug-in solutions for adding power mobility for active wheelchairs. There is a wide number of power motor add-ons to help solve the autonomy issue and partially relieve the physical fatigue and strain on the upper limbs. Pushing and pulling add-ons are equally efficient compared to manual propulsion, but they have negative aspects as well. For example, front casters risk getting stuck while the back motor is still pushing, causing injuries, and the front extra pulling motor reduces maneuverability, limiting

the use of the wheelchair indoors. Additionally, what is lacking are the advantages of the self-balancing techniques that support physical rehabilitation, such as those provided with the APW. The average cost of an add-on is about US\$ 4,000 and is still high for low-resource settings. The future aim of technological research should be to develop lighter and cost-effective self-balancing add-on components to transform any active wheelchair into an APW, thereby bringing their positive advantages to the end-users across the globe.

As the 2019 UN High-Level Meeting on Universal Health Coverage approaches on 23 September governments need to be prepared to implement its Political Declaration whose text[22] on disability states that countries will “Increase access to health services for all persons with disabilities, remove physical, attitudinal, social, structural, and financial barriers, provide quality standard of care and scale up efforts for their empowerment and inclusion, noting that persons with disabilities, representing 15% of the global population, continue to experience unmet health needs”.

”. If the world is to live up to the promise of universal health coverage by 2030, which is one of the main goals of the 2015 United Nations Sustainable Development Goals (SDG) [23], it must prioritize the provision of assistive technologies that best meet the needs of people with disabilities, and allows them the highest attainable standard of health and full inclusion in society which is their basic human right[22].

### **Conclusions and future developments for active powered wheelchairs**

A new paradigm exists for the evolution of the active wheelchair into an active powered wheelchair. Promising preliminary results from studies in Italy provide evidence that APWs can help avoid some long-term health issues associated with active wheelchair use. Larger clinical studies with APWs are necessary to collect bigger and wider datasets, particularly to understand in-depth the clinical effects of the self-balancing technology on the human body. In that way, it will be possible to develop rehabilitation guidelines and practices that continue producing positive health effects seamlessly outside the hospital setting. An important goal is to harness current technological capabilities to allow the design of APWs to be adaptable to changing the health and muscles capabilities of the APW end-user.

Innovative multidisciplinary teams and processes, working with lean innovation and validated learning approaches, within the framework of Agile Customer Thinking, are key to developing APWs and other related digital and mechatronic technologies that can further improve the quality of life and autonomy of a large number of people with disabilities by addressing their most important unmet needs. This manuscript is a call-to-action for all stakeholders to work together to develop innovative assistive technologies and processes to help make universal access to essential assistive technologies a reality, because the time to act is now, and no person with a disability should be left behind.

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