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Assistive technology products: a position paper from the first global research, innovation, and education on assistive technology (GREAT) summit

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ORIGINAL RESEARCH

Assistive technology products: a position paper from the first global research, innovation, and education on assistive technology (GREAT) summit

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ABSTRACT

This paper is based on work from the Global Research, Innovation, and Education on Assistive Technology (GREAT) Summit that was coordinated by WHO's Global Cooperation on Assistive Technology (GATE). The purpose of this paper is to describe the needs and opportunities embedded in the assistive product life-cycle as well as issues relating to the various stages of assistive product mobilization worldwide.

The paper discusses assistive technology product terminology and the dangers of focusing on products outside the context and rolling out products without a plan. Additionally, the paper reviews concepts and issues around technology transfer, particularly in relation to meeting global needs and among countries with limited resources. Several opportunities are highlighted including technology advancement and the world nearing a state of readiness through a developing capacity of nations across the world to successfully adopt and support the assistive technology products and applications.

The paper is optimistic about the future of assistive technology products reaching the people that can use it the most and the excitement across large and small nations in increasing their own capacities for implementing assistive technology. This is expressed as hope in future students as they innovate and in modern engineering that will enable assistive technology to pervade all corners of current and potential marketplaces. Importantly, the paper poses numerous topics where discussions are just superficially opened. The hope is that a set of sequels will follow to continue this critical dialog.

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➤ IMPLICATIONS FOR REHABILITATION

- Successful assistive technology product interventions are complex and include much more than the simple selection of the right product.
- Assistive technology product use is highly context sensitive in terms of an individual user's environment.
- The development of assistive technology products is tricky as it must be contextually sensitive to the development environment and market as well.
- As a field we have much to study and develop around assistive technology product interventions from a global perspective.

The context of assistive technology products

This paper is based on work from the Global Research, Innovation, and Education on Assistive Technology (GREAT) Summit that was coordinated by WHO's Global Cooperation on Assistive Technology (GATE). GATE is a global initiative that was developed to realize the obligations of the Convention on the Rights of Persons with Disabilities (CRPD) towards increasing access to assistive technology, particularly, article 32 of the CRPD. The GREAT Summit objective was to debate and galvanize action on GATE's global priority research agenda to improve access for everyone to high-quality, affordable assistive products worldwide to lead a healthy, productive and dignified life, and to look more closely at the critical areas of innovation and education [1]. Dozens of presentations and dynamic discussion, including 91 e-poster snapshots [2] were presented covering all aspects of assistive technology. Numerous authors focused on assistive technology products.

The GREAT Summit was designed to revolve around five "P"s: People, Products, Provisioning, Personnel and Policy. This paper discusses issues and ideas pertaining to the research, development, design, manufacturer, identification, distribution, selection and

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acquisition of appropriate assistive technology (AT) products. Superficially, products seem to be the nexus of AT, however, the five Ps reflect the scope of the GATE GREAT summit. While this paper aims its scope on the technology, products are in a larger context. This relationship was formally acknowledged three decades ago in the U.S. Technology-Related Assistance for Individuals with Disabilities Act of 1988 (TechAct) [3]. The legislation included two definitions, one for AT Devices and one for AT Services. This is a critical concept to overtly recognize. No governing body, funding agency or society should mistake that, making the technology available to a population is sufficient. Assistive technology products are key, but reside in the overall mapping of an integrated set of five Ps.

That said, there are many unique aspects of products that are not directly linked or integrated with the other four Ps. For example, while the process of product envisioning and development depends on personnel, is driven by user need, and is supported by policy, the product development process primarily relates to assistive products. Other key areas of discussion in this paper include a brief overview of the definitions of AT, product roll-out, the manufacturing process, the importance of technical and process standards, the influence that universal design has on products, and the measurement of the outcomes and impact of using assistive products.

Thus, a key purpose of this paper is to describe the needs and opportunities embedded in the assistive product lifecycle as well as issues relating to the various stages of assistive product mobilization worldwide. The paper contextualizes the product lifecycle and relationships with the various stakeholders to the designs and functions of assistive products. Lastly and importantly, the paper predicts issues that a global implementation system will face if it does not consider key facets of the product design and rollout. Generally, based on the wisdom of the 2017 GATE GREAT meeting in Geneva, the strategic development, manufacture and distribution of assistive technology products will likely revolve around considerations such as those outlined in this paper. Underlying the entire discussion is a critical concept that we cannot forget as we focus on products. Assistive products work best when they are matched to the needs and goals of the individual, and the environment in which the activities are or will be performed [4,5].

Terminology and common understanding of assistive technology products

The definitions of assistive technology products can mean different things to different people depending on context. And there are many definitions of assistive technology products. While a review of related definitions could be helpful, it can also be confusing. Definitions of assistive technology range from the International Organization for Standardization (ISO) [6] to an early formal definition of AT device and AT service was codified in U.S. legislation in 1988. Formally classifying types of products that help people with disabilities have often been driven by legality and policy to define what would be paid by a funding agency. Importantly, definitions often discriminate between assistive technology products and services that support the effective implementation use of products.

The World Health Organization and its global initiative, GATE has clarified terms for more global purposes. GATE defines "assistive technology" as a more encompassing concept that includes systems and services and "assistive products" as a more focused term about the devices themselves. See Table 1 for the definitions that are also available on the GATE website [7].

The GATE definitions emphasize AT as enhancing functioning, and not as being medical or health interventions. We acknowledge that some research and practice areas of assistive technology, such as robotics and rehabilitation have overtly divided technology application into the categories of (a) therapeutic robotics and (b) assistive robotics.

Table 1. GATE Definitions of Assistive Products and Assistive Technology Systems.

Assistive product is "any product (including devices, equipment, instruments, and software), either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing" [63].
Assistive technology is the application of organized knowledge and skills related to assistive products, including systems and services. Assistive technology is a subset of health technology.

While this paper will use the GATE terms and definitions for this paper, we also recognize varied delineations used by specialty groups of researchers and practitioners when discussing assistive technology and assistive products. For example, assistive products are occasionally discussed in the context of technology types overall. In 2017, Smith articulated a set of four broader definitions of technology to the 100th Centennial convention of the American Occupational Therapy Association. Smith defined Assistive Technology separate from Therapeutic Technology, Environmental Technology and Occupational Role Related Technology [8]. These were delineated based on the purposes of the technology and to be inclusive of everyday technology used by general populations as well as the technologies used by people with disabilities. Occupational Related Technology (ORT) is the technology used by everyone in their everyday activities, such as the telephone, the computer, the bicycle and the television. Environmental Technologies (ET) are those used by anyone because they are publicly available in the environment, like lever door handles, elevators, ramps, braille signs, or public audio messaging. Therapeutic Technologies (TT) are those products that serve to help remediate, teach or improve skills such as strengthening equipment, cognitive training software or educational multimedia. Lastly, Assistive Technologies (AT) are personal products used as supports for people to optimize their function, independence and participation in society.

These relationships are described in Table 2 and pose several intriguing perspectives on these four types of technology. First, this delineation of technology types carries some face validity. By definition, these technology types differ by their purposes. They also differentiate between how the products are typically invented, financed and implemented. This has interesting implications for the consideration of alternate innovation, financing or implementation models. Second, the table overtly highlights the role (or missing role) of the person with a disability. Historically, people with disabilities, as end users have been missing in product development. This table (Table 2) highlights that at a minimum, knowledge of people with disabilities is needed. As is described later in this paper, often this means people with disabilities must be directly and pervasively involved in all phases of the product lifecycle, from idea generation to outcomes measurement. Third, the table suggests that assistive products extend beyond health applications. ORT and ET obviously span technology uses to improve functional access to the community participation in general, including employment. Perhaps this points out that AT is a parallel concept that is broader than a focus on health. Lastly, depicting these four types of technology generates the question of, "How distinct are they?" and, "Do products morph between the types?" We know products that were initially conceived as assistive products can transition into the mass market as Occupational Related Technology such as OXO kitchen utensils, or home environmental controls or door lever handles. Likewise, a Therapeutic Technology such as exoskeleton robotics which seems

to be shifting to the combined assistive/therapeutic domain. The relationships of these types of technology reveal a rich area of future study and research.

Critical to the discussion of assistive technology products is the recognition that the array of products crosses a wide breadth of categories. Any given stakeholder of assistive technology products might bring a limited perspective of assistive products based on personal experience. In this discussion of assistive products, though, is it critical to include the full scope of products.

The ABLEDATA database in the U.S. defines 20 categories of assistive technology products ranging from transportation, walking, safety and security, orthotics, housekeeping and recreation. Over the years, in any given period, the ABLEDATA database has cataloged from 30,000 to over 50,000 assistive technology products in this spectrum of categories [9]. Other related databases of assistive products and related resources include "assistivetech.net" as the U.S. "national public website on assistive technology" [10] and European Assistive Technology Information Network (EASTIN) in the European Union. EASTIN is "Your source of information on daily living equipment in Europe" [11]. In Australia, the National Equipment Database (NED) is run by the Independent Living Centres Australia and provides 24 browsable domains of assistive technology to help find available assistive products [12]. Citing these databases is not to express the adequacy or utility of their data, but highlight the breadth and quantity of the data as well as the value the community has placed on such information.

The ISO 9999 is an international terminology standard of "assistive products for persons with disability" that includes 194 pages of a structured taxonomy and classification of assistive product terms that covers domain to inform installation of products, non-technical solutions such as service dogs and medical related products such as implants [6]. Assistive technology categories can be matched directly to a functional activity listed in the WHO International Classification of Function (ICF) [13]. Some assistive technology products address a lower level of functional impairment and contribute to improved function across many activities. For example, products that address limb loss improve function across many upper-level ICF categories of activity and participation. Similarly, for limited reach or hand dexterity, control adaptations such as extended levers, pointers, and switches can improve functional access to many activities.

To help simplify communication to member states, government agencies, service programs and populations of people in the need of assistive products, in 2016 the WHO GATE Initiative defined "Priority Assistive Products" and created a Priority Assistive Products List (APL) of 50 categories of technology [14]. These products include all four types of technology listed by Smith [8] and range from Global Positioning System (GPS) locators, to hearing aids, to ramps and grab bars, to pressure relief cushions and mattresses.

The dangers of applying assistive products outside of the individual user's context

It is important to recognize that AT products are first and foremost products. The best practices for designing, constructing, testing and deploying new products in the marketplace have been codified by industry over the past century. The Product Development Manager's Association (PDMA) documents these best practices for global industry use [15,16]. Product development practices assume the new product's conception, research and design (R&D), production, deployment and support all occur within and under the control of one company or a tightly coordinated network of companies.

This assumption does not hold true for products representing small or niche markets identified as serving a national need. Such markets may lack the economic incentives for private companies to invest in new or improved products, either because they lack the front-end investment capital, or because regulatory requirements or reimbursement policies do not deliver sufficient back-end return on the investment [17]. In these instances – such as with AT products – public government agencies direct funding towards universities or nonprofit agencies, for the purpose of conducting the initial R&D with the expectation that the eventual project outputs will be acquired by existing companies via license or purchase. Thus, the assumptions underlying the PDMA's best practices are not met because the product development cycle involves a hand-off of ownership and control between the initial R&D performer and the eventual product manufacturer. These government-funded R&D projects may also generate noncommercial product outputs such as Freeware applications, Do-it-Yourself kits, Industry Standards and Clinical Guidelines. All of which are relevant to AT industry activity but not necessarily coming from inside the companies comprising that industry [18].

To compensate for the gap between the source of R&D and destination for product manufacturer and deployment, the U.S. government sponsored a program to generate evidence-based models linking the scientific research, engineering development and industrial production phases [19]. The four resulting Need to Knowledge models and an interactive tutorial are all now freely available for download and use [20]. The models contain PDMA best practices while serving as a bridge to the contextual factors most critical to assistive technology product innovation. Several models have been proposed over decades to depict assistive product implementation processes and theories of practice.

Product lifecycle

Assistive technology products are also viewed similar to any consumer product. They require a set of key components that comprise a market cycle. In 1987, the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) published

Table 2. Type of Technology and Associated Inventors, Funders, and Providers.

	Occupational Role Technology	Environmental Technology	Therapeutic Technology	Assistive Technology
IdealInventor	Anyone and Everyone	Environment designers, and construction personnel, especially people who know people with disabilities	Educators, therapists, and health providers, especially people who know people with disabilities	People who know people with disabilities, people with disabilities themselves, and the design community
IdealFunder	Users and Consumers	Owners of places and spaces like businesses and governments	Education, health, and vocational agencies	Education, health, and vocational agencies
IdealProvider	Sales people	Designers and construction companies, especially those who know the needs of people with disabilities	Educators, therapists, and health providers, especially people who know people with disabilities	Assistive technology trained specialists

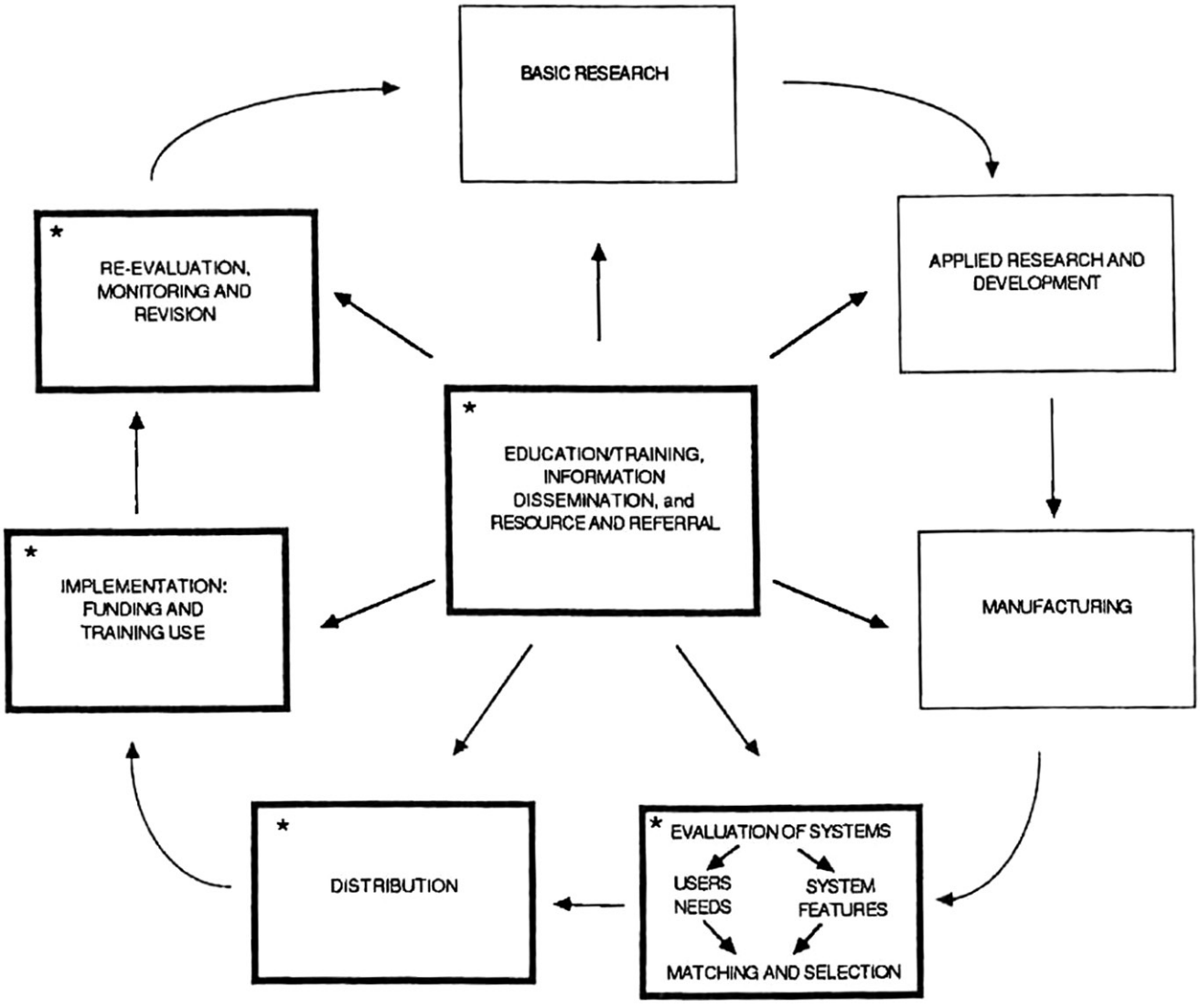

Figure 1. A product life cycle.

a monograph called, "Rehabilitation Technology Service Delivery: A Practical Guide". In the guide, the first chapter depicted the models of assistive technology service delivery and a product life cycle. This product lifecycle described stages from applied research and development to product use outcome measurement [21]. Figure 1 depicts this cycle. This cycle was key to understanding that assistive product implementation was not how any one stakeholder from one perspective might view the process. It was more complex with more key components that only worked if all components were functional.

These fundamental product driven steps begin with (1) product needs identification, leading to (2) product R&D, (3) manufacturing, (4) marketing and distribution, and the (5) application of products that includes evaluation and support. The final step was (6) measuring the outcome that informs the need for the cycle to continue. Importantly, central to this product life cycle was the education of personnel trained to carry out each of these steps. This is a generic process with each step enabled by professionals ranging from the researches to the inventor, manufacturing engineer, to the business person, not to mention the disability services provider and, of course, the user and the people in their user environment. This older product life cycle model has been improved with more recent emphases on the detail of technology transfer and more modern view that included an entrepreneurial and international context. For example, Jefferds et al. and Pearlman et al. highlighted a number of technical advances and approaches for design, manufacturing that could increase production in low-income countries [22,23]. Many models now include the payor as a key factor to how the product cycle is incentivized [24], the regulatory impact for how they create barriers or open doors for new products, and due consideration of the myriad technical, market and customer analyses that are critical to progressing through the new product development process [25]. Assistive product rollout and survival in the U.S. now has developed a history of product success or failure based on whether they have secured the billing codes and/or federal agency approval for payment or distribution, respectively. Newer models also stress the role of the consumer and often place the user of the product user central in the model [26].

The HAAT model (human, activity, assistive technology)

The Cook and Hussey textbook has been one of the seminal resources in technology products as its first edition was comprehensive and formidable for its time in 1995. Of note, Cook and Hussey articulated a model with key domains of consideration

during product selection. This model, called HAAT is still prominently displayed and has been robust over time. Key components of the model are that the Assistive Technology is used in conjunction with the Human that encounters limitations to their performance in Activities. Importantly, the assistive technology intervention occurs in a context that helps frame the challenges and intervention [27].

Assistive technology service method (ATSM)

Assistive technology provision for international contexts is also well stated in Assistive Technology Service Method (ATSM) [28,29]. The ATSM is an ICF based process standard for use across disabilities, professions, and contexts of provision. The ATSM is intended to work with rather than displacing any existing professional standards of practice. With the ATSM, AT provision begins with an assessment of the person and environment, establishing a disability and ability baseline, and developing an intervention strategy. Candidate AT products must then be identified and specific AT products selected and acquired. A recent large interdisciplinary study of expert AT providers in the United States found that providers were generally strong for AT assessment but weak for AT product identification, selection and acquisition [30]. While this study is limited to the U.S. AT providers, there is no obvious rationale to expect that this is not a general problem across international contexts. The Assistive Technology Device Classification (ATDC) is an ICF and ISO9999 based tool used in the identification of candidate AT products and the acquisition of specific AT products [31]. As input, the ATDC uses information commonly derived from AT assessment. As output, the ATDC identifies candidate AT products classified against the ISO9999 with links to AT product sources and descriptions [32]. Candidate AT products might, for example, represent the 50 categories of the Priority Assistive Product Listing plus additional AT products identified by each nation [14]. Selection of the most appropriate AT product requires further consideration of environmental covariates such as psychosocial factors, product usability by the user in context and physical environmental factors.

Matching person and technology (MPT)

The MPT is another well-known and important tool used in the selection of AT products [33]. Like Cook and Hussey, the MPT clearly explains that ultimately, the appropriate use of assistive products must be person, activity and context-sensitive; with due consideration for social as well as physical environment. The MPT, further highlights that one size does not fit all users, activities and situations. This is true on both the micro and macro program level; for matching an individual product to a person or selecting an assistive technology distribution program to a region. An obvious example is the electronic assistive device that requires easy and frequent access to electricity to recharge batteries. Whereas this might be perfect for a person who lives in a large city, a person in a rural area who only has access to electricity at central locations or only periodically during each day may require a different type of technology. Distributing a "one-size fits all" assistive product may result in limited usage, and poor technology adoption. Moreover, a poor person and technology matching device might not only result in nonuse but can actually harm the user or other people in the user's environment and lead to reluctance to try other or additional products [4,34].

Context sensitive situations of product usability, however, are often subtle. Nevertheless, they may be as consequential in affecting a poor outcome. For example, a pointing communication board may be a great match for a student in their school, but without understanding the home environment and how the family or other personnel in the home or from health care services communicate at home, a special communication system for the home might be neglected. Thus, the system may be set aside at home only to sit in disuse, or worse, it may become lost or destroyed because it was perceived as extraneous to the home environment.

The danger of product rollout without a comprehensive plan

The need for understanding context emphasizes the need for creating a strategic plan for assistive technology implementation that includes the user needs and goals, product and the services. Many products cannot be distributed without competent evaluations and properly trained service providers that are capable of eliciting user needs and goals. Matching assistive technology products must include a needs assessment process with appropriate assessment instruments and personnel who are trained to work with people with disabilities and, as appropriate, their families to perform these assessments [35,36]. Products cannot effectively be distributed without a replacement and loaner plan. Several assistive products need to be trialed for a short period of time before deciding on its appropriateness for a specific user. While this process is commonly available in high-income countries, it presents an obstacle in middle and low-income countries, especially when considering the extensive amount of time needed to ship and acquire an AT product. Additionally, assistive products do not last forever. Whether a child grows out of using a device or a device breaks, the need for replacing a product is almost inevitable. In mainstream industries product replacement is a natural part of the strategic distribution. When implementing an assistive product distribution system, a parallel system based on expected product reliability and obsolescence must accompany the rollout.

Important for us from a GATE GREAT perspective is that a plan intended to have worldwide impact needs to consider these stages of product rollout. Our plans must intentionally and strategically incorporate these steps.

Product development process: the push-pull of product design and the need for both

A debate persists concerning the optimal source for technological innovations – should they be pushed out (supply-side) from R&D laboratories or should they be pulled in (demand-side) to the marketplace [37]. This debate is rendered moot in the context of Assistive Technology products, because for products intending to generate beneficial impacts for the user, the product development process must be "pulled" by the consumer community. In fact, the steps of the product lifecycle mentioned just previously imply that product development is based on a prior needs assessment. The concepts of client-oriented practice and participatory action research all emerge from this philosophy. The best product is one for which the consumer understands the need and readily adopts the product to meet the need.

We have all seen products that have been designed and even manufactured for people with disabilities, where it was obvious that users were not consulted and the ultimate product displayed such impersonal esthetics or dysfunctional human interface that virtually no consumer would do more than quickly examine and discard the product without purchase. Most technology transfer models, now, overtly emphasize the discovery phases of product

invention and development so consumers are consulted early and often suggests the importance of prototyping often along the development by creating "look like", "feel like" and act like," prototypes that give the potential user many opportunities to weigh in on the design [38–40]. This new culture of human-centered design and inclusive design aims to move AT products from having marginal appeal to more universal appeal.

Conversely, engineers, designers and inventors continue to praise the idea of disruptive technology; occasionally "push" is needed as a "pull" might be absent. Not all potential consumers can visualize a product until they can try it out and use it for a span of time in the natural environment. A new product or system that is not seen by the typical consumer as viable, but somehow its innovation catches on and becomes adopted by the masses as acceptable and even desirable. Often these products are not initially viewed as preferable as they are so different from mainstream consumer experience. These products are often "pushed" through careful marketing and encouraged into mass adoption. The phenomena of fads, viral media explosion, "build it and they will come", and "the hundredth monkey effect" are based on concepts surrounding product push without a preexisting needs assessment. (The hundredth monkey effect is an unverified account of a monkey colony where a technique was slowly adopted by monkeys until common usage reached a critical number (100) when the entire colony then rapidly switched over to the new method) [41]. The opposite approach is a product "pull" where consumers' need and preferences are well understood and designers strive to serve them. The relevance of assistive product Push or Pull to worldwide assistive product adoption and distribution is un-researched and therefore left to speculation. Which strategy might be more appropriate for assistive products that target the widest public adoption? Perhaps neither is best and both are important rollout strategies. Depending on a given context, Push, Pull or Push/Pull may be the best strategy. Various combinations are needed and will vary based on the human, societal, environmental and regulatory conditions. The importance of understanding these methods is to be aware of the approach to be used and that whatever used is deliberate and assessed, so a product development process can shift or adapt in approach if necessary.

The need to learn from past experiences and those of others

Georg Wilhelm Friedrich Hegel is credited for declaring that, "We learn from history that we do not learn from history." Perhaps some nations and industries have the resources to always learn from a new and resist learning from history, but the relatively fledgling assistive product field is sufficiently small that it needs to at a minimum consider our history as we move forward. Also related is another quote worth referencing from William Gibson, "The future is already here – it's just not very evenly distributed". This highlights issues around access, affordability, and awareness. It is critical for potential users of a product to be aware of the possible uses of a product and its availability. The higher income nations identified many years ago that product awareness is the key and as mentioned previously, centrally funded information databases. Products may not be available in some lower and middle-income countries (LMIC) today. But when products become available, the equal distribution will require awareness of product availability. Easy access and public database access will need to be rolled out simultaneously to product availability. Real and perceived uneven product and information distribution prompts a few observations about assistive technology product development and worldwide distribution.

Nations are not born with an assistive product industry

While assistive products have been with us as long as we have used tools, the overt discussion of assistive technology formally and applied and funded to help people with disabilities is relatively young. Harry Everest and Hebert Jennings created the first steel folding wheelchair in 1932. The first successfully marketed low technology button hook was developed in the basement of Fred Sammons' house in the 1950s. His "low tech" assistive technology empire developed over the 1970s and 1980s. While today we talk about the potentials of personal assistive robotics, smart homes, and mobile technologies, these only started a few decades ago with small labs driven by few passionate entrepreneurs, researchers and inventors. Many fresh solutions may be created by a new wave of passionate business people, students, or people with disabilities and we need to encourage all of them.

Low and middle-income regions have some exceptional assets

While perhaps contrary to popular belief, some low and middle-income nations and regions may be better resourced for innovative discovery than high-income countries. Mobile phone adoption provides a prominent example. Higher income countries had a preexisting commitment in infrastructure with telephone lines running throughout and between cities and even into rural areas. The lower income regions did not have this previous economic handicap to hold back investment in a new system. Thus, they were more ready for mobile technology than higher income regions and led the world in mobile phone adoption.

Lower income regions also have family, community units and local governing structures that may be more supportive of cooperative and innovative initiatives than some of the competitive traditions of higher income regions.

The assistive product industry when considering lower income regions should identify what is unique to their local resources and take advantage of the unique cultural and other contextual factors that might also include unsuspecting subtle or overlooked resources. Several successful examples of utilizing locally available resources were presented in the Summit to resolve the shortage in the availability of some essential AT products [42,43].

The assistive technology industry has the opportunity to examine past/current successful practices

The Fred Sammons story, for example, involved the development of low tech products in his basement that became a multimillion dollar company [44]. This concept could be transferable to local innovation shops and research centers across the world. Alternatively, perhaps a centralized program like the one being generated in Australia through the (NDIS) National Disability Insurance Scheme will provide important models that could be replicable by another nation. This follows a period of time where our Australian colleagues described their assistive technology industry as an import industry. Alternatively, a case study in Brazil might look substantially different than Australia as the culture in Brazil tends to encourage local industry for production and distribution. In Canada, the ORTC (Ontario Rehabilitation Technology Consortium) is another example. ORTC was given the mandate and funding from the Ministry or Health to research and develop local (Ontario) assistive products. The U.S. also innovated with a federal initiative, by funding the Small Business Innovative

Research (SBIR) program. This national level program energized innovation broadly across agencies and continues to enable a larger group of entrepreneurial thinkers, designers, and developers.

The example of Fred Sammons, also provides insight into the advantages of creating a product line with a range of products from the low-cost economical products to the higher cost more esthetic products. Early in the design of the Fred Sammons catalog, Fred decided to create products that he labeled "BeOK" products as the economical versions of products such as the button hook, the rocker knife, or the plate guard. (The original BK from which BeOK emanated was from Button King, the original name of his company after the button hook, his first viable product [44]). Concurrently, he developed and distributed products with more sophisticated and esthetic product presentation, but with a bit more cost. This strategy is one to consider across all assistive technologies in order to be inclusive and considerate of consumer needs and available resources within various settings/contexts.

Overall, a region might consider the policy and cultural environment around product research and development, marketing, manufacturing, distribution. Depending on the local scenario, careful examination of case studies that relate most closely could be prudent. The "Snapshots" being generated at this GATE GREAT Summit may provide an array of windows into such innovative practices.

The "sweet spot" of product development

Several dilemmas surround product development. Some seem like dichotomies, others as continua. These highlight advantages, disadvantages, as well as tradeoffs in the product development environment. A sweet spot of product development is the right position on each of these dilemmas to best match the development and market environment. These dilemmas span purchasing system constraints such as the degree of external control of product purchases, to the product development culture related to quality standards. While many of these dilemmas are worthy of significant discussion related to assistive product development it is beyond the scope of this paper to describe these in detail or discuss the ramifications of these issues. Future papers should expound on these issues. To start the discourse here, examples of these considerations include the:

- Degree of flexibility of product purchasing (mandated products versus choice).
- Level of desire for following quality product standards.
- Targeting specific disability population of users specific versus universal use and therefore, universal design.
- Potential and desire to embed methods of eliciting outcomes data into products.
- Safety and quality goals versus availability and timeliness.
- Product availability with or without professional evaluation.
- Creation of manufacturing infrastructure or lack of infrastructure.
- Guidance through regulation versus more laissez-faire approaches without regulation.
- Amount of user training necessary for effective product use.
- Professionals role as gatekeepers or curators of technology options.

A theme arches over all of these topics. When an assistive product program is created and set in motion, a deliberate data collection and evaluation of the process should be embedded in the development program. Data-based decision making such as selecting design features on documented needs and preferences of potential users is key a sound development processes. Moreover, as the assistive product field is still young, we have much to learn from data we collect surrounding our product development processes. In fact, the sweet spot of product development depends on testing as a critical activity. Products need to be tested at several junctures of product development, use, and as products move to discontinuance. Numerous decisions must be made during a product's lifecycle. Knowing the costs of producing a product and an on-going determination of its effectiveness assists in further product development and future revisions. However, developers must acknowledge that data on product usability and product use do not magically appear. Testing at all phases must be deliberate, structured and funded based on the user's experience (UX).

While this paper is not a tutorial on product testing and evaluation, a quick review of types and phases of testing is prudent. First, we emphasize that testing occurs in all stages of a product lifecycle. For example, when a new idea is being considered for development, the idea must be tested with possible users and experts in the application domains. A new product such as an electronic eating aid should be described to consumers, families and professionals who interact with people who have eating/feeding challenges. This product once prototyped needs to be tried with users. These trials must be documented with UX notes and professional observation and analysis. The product itself needs technical testing for many variables such as durability, safety and functionality. Once the product is available, more detailed data must be collected about the conditions for which the product works (or does not) and among which relevant populations of users. Finally, the costs of actual product purchase and use, along with functional outcomes and impact must be collected.

Unfortunately, these often are missed and critical product lifecycle decisions are made without the evidence and objective information. This frequently means decision makers use their best subjective judgement, depending heavily on guess and personal experience.

Besides the importance of testing and collecting data at each product life cycle stage, the previous discussion also points out the importance of the nature of the data. Objective evidence is critical as are subjective perceptions and documented experiences of all the relevant stakeholders as each will have a particular interest in the product (design, manufacturing, use, etc.) thus leading to differently valued outcomes (adoption, benefit, etc.) [45].

Technical testing typically assumes that a funded laboratory facility is needed. Often forgotten in assistive product testing, however, is that usability, accessibility and outcomes assessment also require resources and a funded assessment team. This may include a full range of consumers, product domain experts, data collection technicians and methodologists to fulfill the competent testing of products to assess their value to end users, the social and physical environment for which they will be used and the community at large. At a minimum, this paper emphasizes (a) the essential nature of testing, (b) the need for deliberate testing, (c) the requirement to cross all phases of development, (d) the inclusion of all stakeholders and (e) the importance of staffing evaluation processes with the appropriate team members.

The need to think "even more" innovatively

The assistive technology field may be accustomed to swimming upstream because the general population does not typically understand assistive products or people with disabilities very well. Thus, as a field we usually think outside of normative culture. However, our global success will require stakeholders of assistive products to think in ways that even they haven't done before.

For example, Do-it-yourself or DIY movement presents an opportunity for people with disabilities. Many helpful products can be made with simple tools and modest skills. People with disabilities and their families can be taught to make reachers, grab-bars, and wheelchair cushions among other items. There are also groups of people, including engineers and clinicians, who are willing to lend their expertise online through design forums, and even to share designs for items to be made using additive manufacturing technologies. People with disabilities may also be engineers, clinicians and business people themselves and contribute on multiple levels to advancing AT. Willkomm authored a book and many dozens of videos on quick and inexpensive prototyping, driven mostly by creative thinking [46]. The same concept can also be applied for enhancing accessibility for people with disabilities. For example, the majority of public transportation in Jordan is not accessible for people with disabilities. A group of therapists worked with some craftsmen to modify a portion of the already available cars, in an attempt to enhance the accessibility of taxis in the country.

The potential of younger minds to open new doors

Today, and historically, assistive products have been fairly traditional in their design competition criteria. Many student competitions are becoming international in scopes such as the 'Enabled-by Design-athon' movement, hosted in England, the US and Australia [47] and at RESNA conferences for more than a decade has co-sponsored such student competitions more may be needed. In the EU, the Zero Project serves as yet another such example.

It is likely that as these competitions evolve and include more and more students globally, they will devote more focus on emerging products that can be produced and distributed worldwide. The assistive technology field can consider more sponsorship of international student design competitions where designers and entrepreneurs from around the world include criteria of low cost or innovative distribution. This also can contribute unique perspectives and stimulate the development of highly capable and innovative assistive technology designers worldwide. Today, inventors, designers and engineers are dominated by high-income nations. A new wave of design competitions could provide support and additional encouragement for designer groups from low and middle-income countries to attempt to encourage a more diverse community of designers.

Additionally, engineers and designers typically receive very little information in their professional training about people with disabilities or design parameters to meet the needs of all possible consumers with or without disabilities. If coursework related to assistive product design and UX were consistently taught in the preservice education programs for engineer and designers, a whole new generation of sensitized and knowledgeable inventors would be produced. The first countries to move this direction in their professional education will quickly move to the forefront of design for all, universal or assistive products.

Designers and manufacturers, not only should consider how universal a product is, but should ways how a product could be made to be more universal and used with broader populations across global regions. The stride toward the global availability of assistive products highlights the differential needs from locale to locale. Yet, we suspect that there are many consistent design functionalities and generic design features. Perhaps a new Global Usability Index is worth exploring. A Global Usability Index could be an interesting way to document the extent of its universality, from manufacturing to distribution and training. A low cost, but flexibly manufactured product, including local materials, and with multilingual tutorials and instructions, would score higher than a product with high cost, one language, and a single manufacturer.

An Open Innovation model that could also help improve the accessibility, availability and affordability of AT to the larger populations that need them is for tried and tested innovations to be made available openly. Such design descriptions should be in the great level of detail presenting the material grades, processes, bill of materials, cost estimates, etc. so that they can be replicated and referenced locally. Having access to the information will empower end users and prevent misuse of the designs. There can be a mechanism where the originator of the design needs to be contacted for use so that some tracking is possible. The primary danger in this model is that local raw materials may not possess the same quality, leading to inferior end-products that may be dangerous to the user. However, for AT where the strength requirements are low (e.g., feeding aids, communication products, etc.), such a model may be viable. The WHO can maintain a database of such products and connect the various stakeholders to increase access.

The importance of a coordinating product development and distribution among stakeholders

Assistive technology product development is often coordinated and delivered by an agency or across several agencies or industries who tend to work relatively independently. In the U.S. this model is common. In this type of model, a business must become cognizant of the range of funding opportunities for the research and development of new products or become successful based on their own entrepreneurial R&D. While this system has demonstrated its capabilities, its efficiencies are limited and many opportunities may be lost among innovators that cannot "figure out" the system for the funding opportunities. A large amount of AT is purchased using the personal or family resources of the person with a disability. This is commonly the case with low-cost and commodity items. Even in cases where technology is provided by a charitable organization, greater buy-in can often be achieved by requiring the recipient to "invest in" and pay a portion of the cost of the device.

Spurring the market for innovations in assistive products in LMIC requires support through a team approach. Developing a good quality product that is appropriate and functional and commercializing it involves high costs and time. Private industry is reluctant to invest in this sector since the market has limited purchasing power. A viable model is required in a situation where no buyer – neither individual nor organization – is ready to bear the cost of development. To address this, LMIC could follow a Grants-Research-Industry-Dissemination model: the government, charitable foundations, or private firms with Corporate Social Responsibility funds could provide Grants to a nodal academic institution to do the Research, rigorous product development and testing with local Industry partners and Dissemination partners, who may be user groups, rehabilitation centers or hospitals. This kind of partnership ensures involvement of all the stakeholders during the product development process. The goal of the grant, typically given to the academic institution to manage while including funding components for the industry and dissemination partners, impacts through the development of an affordable product that can reach the maximum number of users who need it. This model provides an incentive to an already established industry (in some related area) or a startup to achieve a user-oriented, market-ready product in AT at little risk and access to a ready market through the participation of the dissemination partners.

Involvement of the users throughout the process ensures that the product serves their needs, enabling greater acceptance in the market.

Challenges lie in the ability of academic institutions to get the necessary grants, manage product development and coordinate diverse teams. To create awareness and facilitate wider participation, regional hubs of WHO can consolidate grants from various sources, create a network of interested industries in related areas (e.g., bicycle manufacturers can expand their product line to wheelchairs), and connect them with NGOs and rehabilitation centers who will be the point of contact for the end users. Encouraging regional and local development will result in the availability of good quality, appropriate, affordable AT to the millions in LMICs whose current options are very limited. The TTK Center for Rehabilitation Research and Device Development in the Department of Mechanical Engineering at the Indian Institute of Technology Madras in India is in the process of commercializing four products currently through this model.

Consequently, we may be able to learn from past or existing technology development strategies and consider new methodologies that might coordinate better across government support, private enterprise innovation, university research laboratories, social service agencies and professional organizations. This is particularly important in the area of orphan technology research and development where the population of users might be relatively small. There is always a special challenge when product development does not anticipate payoffs well on the financial investment. These products may have small consumer audiences when with any of the promotional entity, but if agencies can coordinate and aggregate their individual users, the base can become sufficiently large to sustain a product lifecycle.

Maximizing opportunities related to the worldwide aging sector

While the aging population across the world, particularly in the more industrialized nations, is of concern to governments and researchers, this may actually be an enormous advantage for the field of assistive technology. People who are aging include people with disabilities and impairments, only early on, having a mild disability or a mild impairment [48]. Consequently, the disabled community in the field of assistive technology may have a major product development opportunity because we already understand mild to severe disability and can innovate products not only for people with severe disabilities, but also for people with mild disabilities including mild disabilities due to functional challenges from aging. Also, provision of assistive products and need of housing adaptations must be considered simultaneously, applying an explicitly user-centered perspective. Since functional decline and activity limitations often come with age, with an ageing population using assistive products, there is a risk for a situation with increasing accessibility problems and activity limitations. Also, in home and healthcare staff needs must be taken into account when assistive products are designed. Significant work has been done in this area [49].

Products for people who are aging also creates an opportunity for the assistive technology field due to the comfort level of assistive technology designers with universal design. Whereas severe disability and the development of targeted assistive technology products may not naturally evolve into universally designed products, many assistive technology device designers understand or can understand the concept of designing across many disabilities and not just one. Consequently, assistive technology product designers can quickly sidestep to create universally designed products that might speak to the aging community in a much larger population for sales of innovative products. The win-win of incorporating universal design and assistive technology product development is not only creating products as functional solutions for larger populations of individuals, but also presents the potential economic advantage with larger manufacturing runs that decrease production costs per unit.

The opportunities in the modernization of manufacturing and engineering in general

Recent phenomena have begun to have a major impact on product manufacturing and its interaction with distribution in the general marketplace. These appear as if they could have a disruptive impact on product availability for people around the world. The possible relevance could be even more disruptive in the field of assistive technology.

The first is the advent of locally distributed manufacturing, i.e., 3 D printing. Computer controlled machines have reduced or eliminated the need for expensive tooling and multiple machine setups; this has made it feasible to manufacturer complex products in small quantities. The advantage of local and distributed manufacturing such as rapid prototyping and additive manufacturing (aka, 3 D printing) is that transportation is not required. Therefore, product availability becomes almost immediate. Products can be created as a customized size or design with immediate delivery. The National Committee on Rehabilitation Engineering (NCRE) in Australia – a specialist group of Rehabilitation Engineers within the College of Biomedical Engineers, part of the Professional Association Engineers Australia, recently drafted and published a technical document on additive manufacturing and 3 D printing, specifically for the AT sector. It's called "Additive Manufacturing" [50].

A second is the advancement of point-to-point distribution through new transportation mechanisms directly linked with manufacturing facilities, e.g., Amazon and Alibaba who are connecting centralized manufacturing facilities to an individual more efficiently than ever before.

The advantage of central manufacturing facilities is the access to extensive expertise and costly facilities. These intense resources do not need to be distributed, but can be focused. Central manufacturing facilities are realistic with fast, reliable and inexpensive delivery systems. Prosthetics and orthotics are leading examples of these i.e., manufacturing and distribution systems in the field of assistive technology. Already today, prosthetists can measure an individual with limb loss, send specifications to a central laboratory facility for production. After central production of the limb, the prosthesis can be sent directly to the prosthetist and their patient for the fitting of the artificial limb to the individual on delivery. Eyeglasses are another more simple example of where this type of system is currently used successfully all over the world.

A third relates to engineering advancement. The internet allows for tele-rehabilitation, new types of power systems enable localized capacity for personal usage and manufacturing, miniaturization opens doors for portability to distant reaches of the globe. These will all enable a new generation of assistive products.

An important fourth opportunity may be developing through increasing global interests in the economic development related to assistive technology products. Besides the WHO GATE initiative, China has added its interest through its unveiling of the Belt and Road Initiative simulating the centuries-old historic Silk Road [51]. This broad-based and bold financial infrastructure investment has been securing the attention of governments and

the press worldwide. This initiative is highly relevant to the discussions of assistive technology product globalization. At the second Global Conference on Assistive Technology 2017 in Beijing, China, the Chinese hosts presented how the Belt and Road Initiative fundamentally includes people with disabilities and assistive technology products as core components of the vision [52].

For such modern manufacturing and distribution systems to manifest themselves in assistive technology, however, requires three key resources: (1) coordinated expertise, likely via the internet, (2) a fluent communication system, and (3) efficient transportation. All of these currently exist in some locations. Where they are not available, planning as a part of the implementation process will increase the likelihood of success. Manufacturing, material, and computer engineering will continue to enable new opportunities. The miniaturization of electronics, lower cost and wearable electronics, flexible products, and smarter products will continue to create new ways for creative designers of assistive products to think larger markets and worldwide infusion.

Product development and market shaping

As has been noted, changes in the ways in which products are being developed and produced – locally distributed manufacturing, point-to-point distribution, telerehabilitation – is blurring the distinction between production and provision per se, and opening up significant markets globally. How then can we ensure that these exciting developments are applied equitably – reaching those most in need or most marginalized, but who may have little purchasing power? Similar challenges have been faced elsewhere with perhaps one of the best known examples being in the supply of antiretrovirals for HIV. Initially, only those who were relatively wealthy could afford to access these life-sustaining drugs. Subsequently, the Treatment Action Campaign [53], the Clinton Health Access Initiative (CHAI) [54], and pooling of purchasing power [55] form donor governments have contributed to shifting the expectation and implementation to treatment access for all. Recently CHAI has, for instance, contributed to shaping expectations in the market through the development of a product introduction guide (see, for example, [54]). Within Africa, the African Medicines Regulatory Harmonisation (AMRH) program has been established to promote access to safe, high-quality medicines, at least in part by influencing market conditions [56].

In the context of global health challenges, USAID suggests that "… optimising markets is only an intermediate goal along that path … to … interventions that serve the public good, … candidates for market shaping interventions include both failing markets that impede health goals and economically well-functioning markets struggling to achieve optimal public health impact" [57]. Of course, there are important differences between pharmaceutical and assistive technologies, but also opportunities to learn from some of the related challenges in creating a production cycle and supply chain that is responsive to social equity. In essence, market shaping is required where market economics fail to provide for social gain in an equitable and fair way. For instance, it may be most economically attractive to producers to supply relatively few products, to relatively rich people, at a relatively high price; rather than more products, to more people, at a lower price. As noted already, it is because assistive technology product development is so often stimulated by innovations in the private sector, that there is an onus on government to ensure the benefits of such product innovation are as available and accessible as possible. While market shaping has been successfully used to promote social gain, it is not synonymous with it and can quite legitimately be used in other types of market intervention [58].

The Officer of Government Commerce (OGC) argues that market shaping can help to create a more responsive market for the public sector by taking a systematic and strategic approach within markets where the public sector operates [59]. This may involve improving the security of supply, reducing over-dependency on particular suppliers; creating a better dialog between the demand and supply side, which can, in turn, allow for better planning for bidding and delivery of products or services, and stronger supplier engagement; all hopefully contributing to better value for money. At a broader level relevant considerations may include public sector market size (Does the public sector constitute a large or small part of the market for the product(s)?), supply capacity (How sensitive is it to changes in demand?), presence of competition (Is there a single or are there multiple suppliers?), predictability of demand (Is the basis of demand transparent?), statutory obligations (Is government obliged to provide the product(s)?), government policy initiatives (How likely are they to impact the market?), and implementation (Are key stakeholders open to change?) [59]. The Assistive Product List [14], discussed earlier, is an attempt to establish an evidence-informed norm for the supply of products that governments should aim to achieve, as a minimum, not a maximum. The list assumes there will be variations according to different needs in different countries, but, like the very successful Essential Medicines List [60], now in its 19th edition. The APL is a potentially important guide to product manufacturers, as it is indicating the range and types of products for which there is an intention to increase demand, and so where a reduction in price for suitable products may effectively be offset by much larger scale production.

The scale of production and reliability of procurement are likely to be critical challenges for assistive products in the decades ahead [61,62]. We hope that international donors may work collaboratively with the governments of less well-resourced countries to pool-procurement of assistive products. This would allow guaranteed demand over a number of years, and the securing of supply chains to the scale required to reach the most marginalized, for access to the assistive products that are a priority in those countries.

Conclusion and summary of the recommended way forward

The design, manufacturing and distribution of products are key parts of the assistive technology lifecycle. This process has many challenges, but worldwide may have many more opportunities. The GREAT Summit allows us to consider these opportunities and plan forward about how assistive technology research and development, as well as distribution, might be effectively promoted, administered and implemented in the world communities of designers, researchers, manufacturers and distributors.

Here are a few product related statements to stimulate future dynamic discussions on a global level on a variety of topics and issues. Hopefully, several follow-up papers will expand the robust discussion begun here and further detail the arguments raised by this paper on the globalization of assistive technology products. Consider the positions of these statements to stimulate the conversation:

- We need to create product lines with a range of costs/quality (temporary and economical and permanent/expensive.)
- We need to create financially sound motivational paths for R&D in low cost/low resourced assistive technology settings.

- We need to think about all 50 areas of products not focus on one or a few.
- We need to assume that we have limited funds so target the largest low-cost impact, while at the same time aggressively articulating the need and acquiring the necessary funding.
- We need to leverage modern technology production facilities (3-D printing, central labs.)
- We must think innovatively to generate new cadres of assistive technology designers, small businesses, manufacturers, and distributors.
- All areas of the globe have unmet AT needs, but they differ depending on climate and geography, available personnel and finances, policy directives, and so on.
- Assistive products must address the needs of the ageing population since the functional decline and activity limitations often come with age. Prevention and public health strategies must meet the needs of the ageing population.
- We need to think about different contexts for AT use and the deployment of different professionals/perspectives to enable and optimize the use of assistive products.
- Interdisciplinary and transdisciplinary research is needed with imperative user involvement/influence.
- We need to train people with disabilities to create and maintain some, and in a few cases, most of their AT, including their needed and desired modifications.
- Assistive product systems require new levels of expertise and methods for assuring appropriate levels of knowledge and skills have been acquired for all stakeholders of assistive product systems.

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