Title:

A Model to Standardize the Procurement and Quality of Assistive Technologies in Less-Resourced Settings

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Keywords:

assistive technology; design; procurement; quality; wheelchairs

Abstract:

There remains a vast need for quality assistive technology (AT) around the world. The World Health Organization (WHO) estimates that 1 billion people need 1 or more assistive products and only 1 in 10 people have access to them, suggesting that the unmet need is approximately 100 million AT products. To address this need and improve the quality of life of people with disabilities specifically, the United Nations (UN) promotes the right to improved accessibility to appropriate assistive technology. Guidelines and policies published by UN and WHO have driven organization-led establishment of programs for improving wheelchairs, prosthetics and orthotics among all ATs. For instance, the WHO Guidelines on provision of manual wheelchairs in less-resourced settings has motivated funding agencies such as the United States Agency for International Development (USAID) to support several projects and initiatives to improve the availability of and access to appropriate, high-quality wheelchairs and trained wheelchair service providers in less-resourced settings (LRS). Two such initiatives are the Consolidating Logistics for Assistive Technology Supply and Provision (CLASP) and the International Society of Wheelchair Professionals (ISWP) that have activities focused on procurement and standards of high-quality, appropriate wheelchairs. These may serve as models that can be applied to ATs and implemented at local and national levels in LRS to improve AT procurement and quality.

Introduction:

There remains a vast need for high-quality assistive technology (AT) around the world and this need will increase with time due to ageing, rise in noncommunicable diseases and increasing number of injuries from road traffic crashes, violence, falls, acts of war and natural disasters (1–7). Currently, more than 1 billion people need 1 or more assistive products and only 1 in 10 people in need have access to one (7). This need is overwhelming in less-resourced settings (LRS) as an estimated 80% of people with disabilities live there (8). In such settings, there is a lack of reimbursement schemes and regulatory oversight of AT products and services, and consequently, when ATs such as wheelchairs are provided, they flow through multiple procurement channels such as donation, small-scale workshops, manufacturing, globalization and multi-modal. Because these channels are often informal and uncoordinated, it can lead to non-uniform product characteristics and quality (9). One of the common channels of provision in LRS is donation of a patchwork of different types of ATs by non-governmental aid and charitable organizations through camp-style distributions. This model of provision although known for providing AT and wheelchairs in large volumes, has been criticized by many experts who report that donated products lack necessary features, appropriate sizes and quality (10–12). Other channels provide products that are built locally, imported or refurbished products from another country through small-scale workshops, dealerships or wheelchair clinics (9,12). Irrespective of the procurement channel, the majority of the AT delivered in LRS is not appropriate for environments and use conditions which is linked to frequent product failures and breakdowns (13–17). Community studies conducted in LRS have reported AT products including walkers, canes, wheelchairs, tricycles and knee-ankle-foot orthosis (KAFO) to fail and be discarded within 3 months of use (14,15,17–19). Failures with these AT products are known to injure users, leave them stranded, and lead to significant secondary health conditions. For instance, without access to a reliable wheelchair, the user may need to stay in bed which increases the risk of pressure sores, drop foot, or spinal deformity and may cause premature death (12,20). Overall, the lack of regulations, funding and awareness has led to provision of inappropriate quality of AT models in LRS which is associated with adverse user consequences.

Improved accessibility to high-quality, appropriate AT to improve the quality of life of people with disabilities is a human right issue recognized by international guidelines and global stakeholders. The United Nations Convention on the Rights of Persons with Disabilities (UN-CRPD) specifically mentions the importance of

ATs in eight of its Articles (4, 9, 20, 21, 24, 26, 29, and 32) (8). Although there is widespread ratification of the UN-CRPD by as many as 177 countries, progress on its implementation is hampered by several challenges including a lack of appropriate community support services and guidance to support member states to implement the necessary changes (21). To accelerate the implementation of UN-CRPD initiatives globally, the WHO in 2014 initiated a program called the Global Cooperation on Assistive Technology (GATE) (22). As a part of this program, WHO recently published a Priority Assistive Products List (APL) that includes a list of minimum 50 AT products selected on the basis of widespread need and impact on people's lives (23). WHO, furthermore, has published guidelines for provision of manual wheelchairs in less-resourced settings and standards for prosthetics and orthotics that specify best practices and recommendations for design, testing, production and supply of these respective AT devices with a focus on increasing their quality (12,24). The WHO wheelchair guidelines define an appropriate wheelchair as one that meets the user's needs and environmental conditions; provides proper fit and postural support; is safe and durable; is available in the country; and can be obtained and maintained and services sustained in the country at the most economical and affordable price (12). Among all ATs available globally, wheelchairs, prosthetics and orthotics, have evolved significantly owing to the collaborative work of international organizations and global experts, and publication of guidelines and policies. This paper draws observations from activities that have been ongoing in the wheelchair sector with application to AT procurement and quality improvement, more broadly.

USAID Wheelchair Program

To support the recommendations in the WHO Guidelines, the United States Agency for International Development (USAID) and other U.S. Government agencies in collaboration with WHO have developed wheelchair service training packages, supported programs in 42 countries and provided over 70,000 wheelchairs (3). USAID has historically funded wheelchair programs that focus on five key areas: Research, Resources, Support Programs, Procurement and Professionalization (25). This paper focuses on specific activities that have been sponsored through the two USAID-funded projects the Consolidating Logistics for Assistive Technology Supply and Provision (CLASP) and the International Society of Wheelchair Professionals (ISWP) that address standardizing procurement and quality of wheelchairs.

Approach:

CLASP, a distribution mechanism that consolidates a range of appropriate, high-quality wheelchairs (26) from various suppliers and promotes appropriate provision. ISWP, a global society that is strengthening wheelchair quality testing standards and disseminating resources on wheelchair design, testing and selection (27). CLASP and ISWP have developed and implemented project

practices and procedures that may serve as models to standardize product procurement (selection and distribution) and operationalize quality standards of ATs in LRS.

CLASP as a Model to Improve Wheelchair Procurement:

In 2014, the CLASP program was launched through a USAID-funded project implemented by UCP Wheels for Humanity (UCPW). The goal of CLASP is to improve the availability of and access to appropriate AT in LRS and to promote quality service provision. CLASP was conceived as a supply solution to ongoing challenges that wheelchair service provider organizations in LRS experience, including limited product variety, extensive lead times, and logistical burdens. CLASP streamlines distribution, expands marketing to ramp up global sales, promotes quality service provision through a network of CLASP Service Partners and promotes industry collaboration to advance a shared agenda.

To improve the availability of and access to AT, CLASP enables ordering of mobility products as listed in the GATE Assistive Product List through a web-based product catalogue (https://www.clasphub.org/products/). The selection of products in the catalogue is carried out through a bidding process guided by a Product Advisory Council (PAC) that comprises of wheelchair users, clinical, and technical experts from different countries with vast experience in LRS. PAC members are selected through a nomination process and serve on a volunteer basis.

CLASP stocks adult and pediatric wheeled mobility devices that come with a standard set of promotion and support materials providing details of a product's performance specifications plus instructions on the proper use and care of the product. The goal of CLASP is for buyers, service providers, and other stakeholders to be able to purchase small-to-large numbers of a range of appropriate wheelchairs and non-wheelchair mobility products from a number of suppliers through a web-based product catalogue. Product sizes, specifications, intended users and support materials (user guide and assembly manuals) are provided on the product page. Spare parts and modification kits are also available. A wheelchair buyer, supplier and/or provider can request for a quote for appropriate products of interest directly through the CLASP on-line portal.

To date, CLASP has been successful at delivering high-quality mobility aids to more than 30 countries in some of the most remote regions in the world.

Multidisciplinary and Structured Selection of Products for CLASP Catalogue

The selection of products in the catalogue is carried out through a structured bidding and expert technical review process guided by the PAC. The bidding process begins with an announcement of an Invitation to Bid (ITB) for seating and mobility products based on product class. Eligible bidders are global

wheelchair suppliers. Each bid is internally developed by CLASP's wheelchair experts with input from the PAC.

Products submitted in the ITB are evaluated through two phases of evaluation as below:

Phase I Evaluation

Interested bidders including wheelchair buyers, suppliers and providers are provided with product and operational requirements, divided by product class each with a corresponding rubric that transparently scores each requirement. A question & answer period allows CLASP to clarify bidder questions prior to embarking on submission. Initial scoring is split between threshold requirements and non-mandatory features. Bidders that meet threshold requirements are invited to Phase II. Threshold requirements are noted as-such within the evaluation rubric, based on the product class. Threshold categories fall under three review domains: product specifications, product quality, and business suitability.

Phase II Evaluation

Phase II review involves two additional review domains are included; product past performance and in-person product review. The review process solicits input from all PAC members who review and score products in multidisciplinary expert teams. Product review is conducted through a hybrid in-person and live streaming approach. The global multi-disciplinary team spans time zones, which pose coordination challenges, but full in-person participation would be cost prohibitive. As such, the hybrid method has been a reasonable compromise.

During the in-person evaluation, the assembly, finishing, functionality and quality of each product are assessed. Group conference calls following in-person evaluations address any concerns and generate consensus. Throughout the process the bidder is asked for supplemental or absent information and clarification. A recommendations report developed and approved by PAC is submitted to CLASP. In the event of a dispute, PAC concerns or need for a tie-breaking vote, an ISWP expert is recruited.

Product selection is communicated to suppliers and over a 6-month period, new products are availed through the CLASP online catalogue.

CLASP Service Partners

The CLASP distribution mechanism promotes provision of appropriate wheelchairs through several mechanisms. One way is through selection and promotion of CLASP Service Partners. The Service Partners are selected through a competitive process in which they are evaluated to be in-line with the 8 steps

for appropriate wheelchair provision stated by WHO. This includes the availability of trained service providers, range of product in stock, and organizational capacity to manage inventory and solicit funds. Service Partners are eligible for CLASP product donations and the partnerships are valid for a period of up to 3 years. As part of their responsibilities and commitment to appropriate provision, Service Partners have to register each newly provided wheelchair online with the accountability of responding to warranty claims, if any. Quarterly reporting on follow up is also required by Service Partners. This allows Service Partners, CLASP, and Suppliers to learn more about consumer satisfaction, and product performance. This feedback is critical to collect field performance of products and in turn, improve their design for better performance. Beyond Service Partners, CLASP buyers are provided information to register each individual wheelchair upon fitting to the end user, encouraged to conduct follow-ups and use CLASP's user feedback form to contribute to the understanding of context-specific product performance.

ISWP as a Model to Improve Wheelchair Quality:

USAID supported several programs and organizations around the world to professionalize wheelchair services and promote greater access to affordable and appropriate wheeled mobility devices and services. The discrete nature of these supported programs across different regions resulted in a wide variety of standards, norms and quality of service (28). To address this issue, in 2015, USAID funded development of the ISWP with the aim of coordinating the wheelchair sector and developing product and service standards. ISWP initiatives are directed by an Advisory board and while the activities have evolved over time, there is a strong emphasis of sector-wide collaboration that has been coordinated through working groups, with focuses on 1) Training; 2) Policy/Advocacy; 3) Product Standards; and 4) Evidence-based Practice. The focus of this paper is to highlight the activities of ISWP's Standards Working Group (SWG) in improving product quality through guideline and standards development. The SWG is composed of representatives from United States, United Kingdom and South Africa with significant field experiences in LRS and expertise in wheelchair design and manufacturing, procurement, and large-scale purchasing. The SWG was established as an open group, where additional members can join at any time, and all meetings are open for participation from the wider community.

The group began their operations in early 2015 with biweekly group discussions via web conferencing. These group discussions were centered around wheelchair failures frequently encountered in the community but not predicted by the published ISO-7176 international wheelchair quality testing standards which include a suite of stability, dimensional evaluation and durability testing methods (13,29). The SWG experts provided informal evidence for the discussion by sharing pictures of broken and inoperable parts that they had collected through their work to demonstrate the types of failures common in

adverse environments witnessed in LRS and rural areas of resourced settings. In parallel with these discussions, a literature review was conducted by a part of the SWG to determine the scope of the evidence regarding wheelchair quality in LRS and the application of ISO or other relevant standards. The review concluded that the current suite of ISO test methods is suitable for testing wheelchair products used in urban environments but not for those used in adverse environments where rough terrains, debris and elevated temperatures are common (13). The SWG then carried out a series of discussions to identify and prioritize additional tests that are required to predict wheelchair reliability in adverse environments. The outcome of these discussions was a list of tests methods that should be developed for wheelchairs used in adverse environments. The group then investigated whether test methods were already published (for example for similar products) through major standards organizations (e.g. ISO, ASTM and MIL-SPEC) that could be used as-is or could be a basis for new ISWP test methods. The priority for developing test methods was determined based on parts that fail most often and their related risk to the user's health and safety (13). Based on this effort, four test methods were prioritized for development: 1) Castor durability testing; 2) Rolling resistance testing of rear wheels and castors; 3) Corrosion testing and 4) Whole-chair durability testing.

In addition, the SWG highlighted the need for a best-practices document for wheelchair design to be used by designers to avoid the pitfalls common in wheelchair design. Part of the SG undertook the activity for drafting the best practices document based on their respective expertise. Wheelchair part and human anatomy drawings were sourced from one of the SWG members and added to the draft. ISWP castor testing outcomes informed some of the castor design guidelines. Once the draft was compiled, feedback was sought from 5 independent wheelchair experts through an in-person meeting. These expert reviewers were nominated by SWG members and other wheelchair experts affiliated with the ISWP. Following review, the draft was revised significantly based on comments and compiled for publication.

Castor Durability Testing

Rough terrains, shocks and corrosive environments cause castors to fail frequently with multiple failure modes, most of which are not simulated on ISO 7176 tests (18,19,30–35). An evidence-based approach (Figure 2) was followed in which evidence available from the three data sources of community, expert review and testing results was iteratively triangulated to develop the test equipment (see Figure 3) and testing protocol (36). Validation of the protocol to community data has led to failures from the community strongly correlate with the representative failures seen on the laboratory-based test (36,38). The equipment and protocol are consistent with ISO/AWP 7176-32 which is a castor standard under development (37).

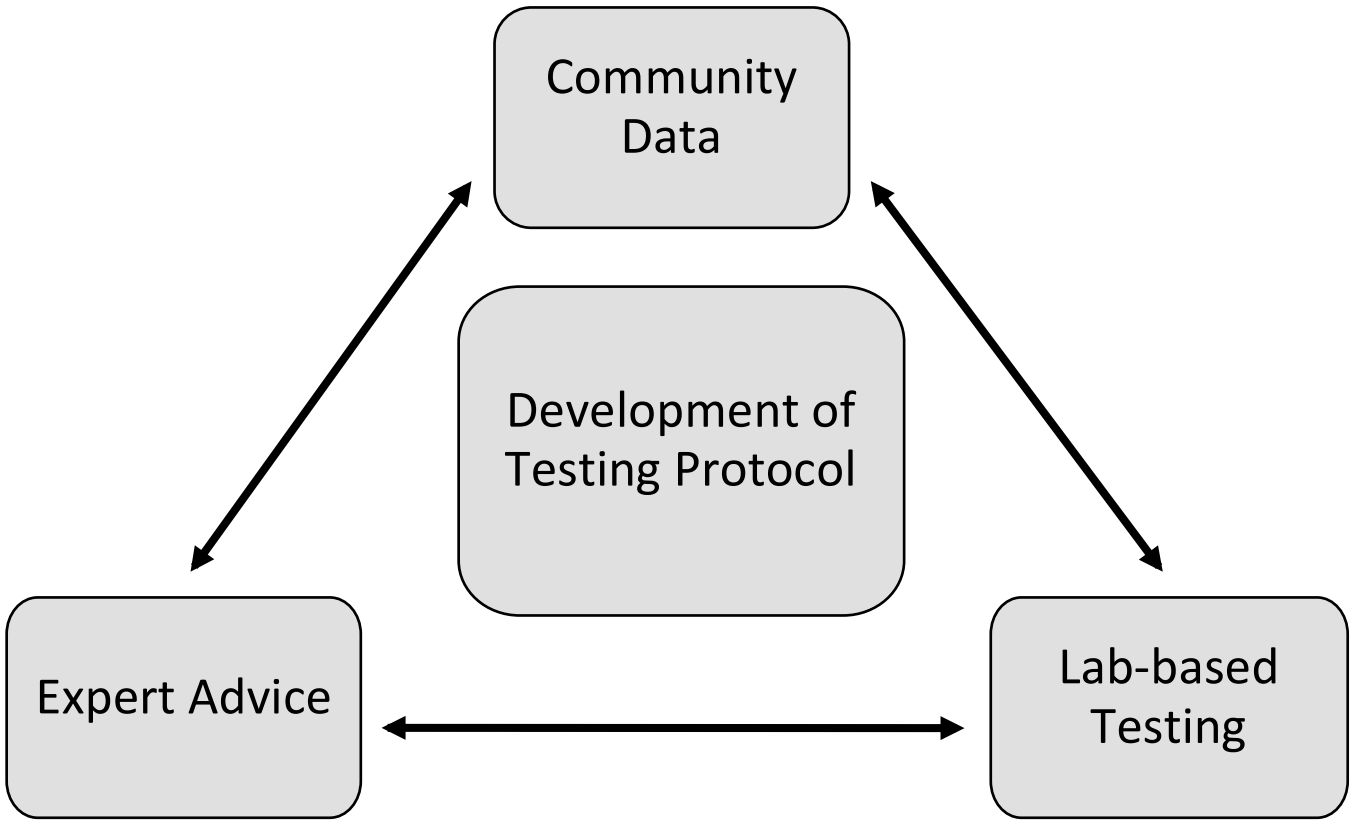

Figure 2: Evidence-based approach for development of testing standards

Figure 3: ISWP Castor Testing System also called as ISWP Chakra

Rolling Resistance Testing of Rear Wheels and Castors

Wheelchairs used in adverse environments are found to be heavy and difficult to roll (12). Wheels, tyres and castors perform differently and differ in rolling resistance depending on tyre's tread design, type of tyre (pneumatic versus solid), camber level, toe-in/toe-out, type of spokes, and play in the axle hub bearings. These conditions are not included in ISO testing. The ISWP Rolling Resistance Test (Figure 4) evaluates the resistance of wheels and castors. Results from the tests allow manufacturers and service providers to select an appropriate design based on use conditions.

Figure 4: Rolling Resistance Testing System

Corrosion Testing

Corrosion of wheelchairs is a universal issue wherein several wheelchair parts such as brakes and bearings lose their operational ability after being corroded. Although ISO testing includes testing in hot and cold environments, it does not test for corrosive, humid conditions to simulate exposure to rainwater or waterlogged in ditches. Hence, corrosion evaluation of specific chair parts is recommended. The ISWP Corrosion Test (Figure 5) includes testing wheelchair parts according to the ASTM B117 standard and evaluating them as per MIL-SPEC and ASTM standards. Such testing assists in evaluating the corrosion resistance of painted and coated parts (36).

Figure 5: ASTM B117-based salt fog chamber for corrosion testing

Whole-chair Durability Testing

The SWG recognizes that wheelchairs suffer from mechanical impacts and shocks, and effects from environmental factors. Environmental factors include different ground surfaces, temperature, humidity, and dirt that are not included in the standard wheelchair test methods. The SWG in collaboration with Free Wheelchair Mission (FWM) is developing a whole-chair test which consists of a 20-foot treadmill that exposes wheelchairs to shocks and drops as seen in the community (Figure 6). Similar to the castor test, the validation of the shock conditions was conducted using acceleration and stress data collected in Kenya (39). To improve product quality, FWM has been continuously testing their products and offering testing services to evaluate other wheelchair designs and components.

Figure 6: Whole-chair Durability Testing System at FWM

ISWP Testing Outcomes

ISWP has tested multiple wheelchair models (with ISO testing) along with testing of wheelchair products with ISWP tests to screen inappropriate products. The outcomes from the ISWP testing work are as follows:

1. Development of wheelchair design and selection guidelines for manufacturers, suppliers, designers, clinicians and users in LRS (36).
2. Design modifications provided to manufacturers and suppliers for improving product quality and reliability (36,39).
3. ISWP plans to publish wheelchair testing standards under development as international standards through the International Organization for Standardization (ISO) (40).
4. Test improvement suggestions for ISO wheelchair testing standards to enable simulation of field-representative failures (36).

ISWP Design Considerations

While developing standards, the ISWP-SWG has published a Design Considerations document to guide wheelchair designers, manufacturers, providers, users and their caregivers on best design practices for wheelchairs used in adverse environments (41). Manufacturers, designers and technicians can apply the design practices for building appropriate mobility products and improving the quality of current designs for LRS. ISWP has been disseminating the guidelines to stakeholders and providers with the hope that more users will receive appropriate, high-quality wheelchairs, enabling them to actively participate in their communities.

ISWP Product Testing Documentation

There a very few independent wheelchair product quality testing laboratories internationally. To raise the wheelchair testing capacity around the world, ISWP has been publishing product testing documentation. Manufacturers and providers can setup test labs to conduct testing of local and imported products to determine their appropriateness and quality. The documentation packets consist of operational checklists, schematics and design drawings. The documentation has been published as open-source and is also being disseminated through the ISWP Resource Hub (27). Documentation is currently available for the ISWP Castor Test, ISO Multi-drum and Curb Drop Test, and Test Dummy (42–45). Further, the SWG plans to develop a Wikipedia of testing methods which will further assist development of wheelchair testing laboratories.

Discussion:

A lack of controls and viable markets in LRS often result in low-quality, inappropriate ATs including wheelchairs being procured and provided that rarely meet the needs of the recipient (12). This has led to poor user outcomes and AT abandonment (14,15,19). To improve the quality of life for wheelchair users, the USAID-funded projects – CLASP and ISWP are helping to standardizing wheelchair procurement and quality internationally. They are generating evidence, standards and resources that have the potential to inform decision-making on design and supply of appropriate wheelchair products globally. These two approaches support each other to improve wheelchair procurement and quality of wheelchairs internationally.

For instance, CLASP relies on the ISWP guidance on the standardized testing (e.g. ISO and ISWP tests) that should be used as part of the product screening during their ITB evaluations. Since ISWP supports standards development for adverse environments, wheelchairs procured through the CLASP catalogue should be high-quality and reliable for use in LRS. CLASP through their relationships with product suppliers can promote the ISWP-recommended tests protocols that support the uptake of the tests into global testing facilities.

Through ongoing monitoring of customers, CLASP collects data on product failures, warranty repairs and replacements in LRS which has been difficult due to lack of programs and provision systems that encourage follow-up, repair and related data collection. Such data can then be used to inform product standards development activities (Figure 2). For instance, the ISWP SWG as well as ISO working groups develop testing methodologies based on product failure in the community, and CLASP's data can then directly be used to inform and strengthen standards development.

Recommendations for Greater Access to Appropriate AT

The wheelchair sector-specific CLASP and ISWP models can be coupled, adapted, and implemented as a national strategic approach to standardize the procurement and quality of AT in LRS (Figure 7).

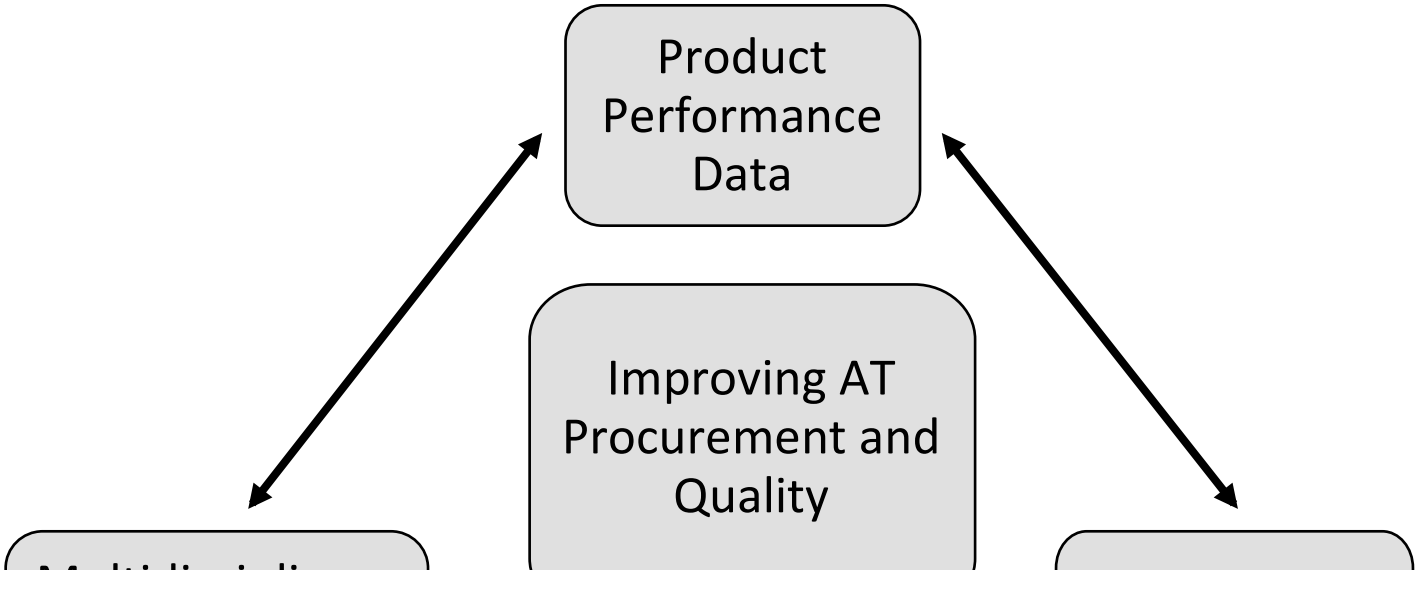

Figure 8: The CLASP-ISWP model to improve access to appropriate AT

A multidisciplinary expert steering committee like CLASP's PAC and ISWP's SWG can be formed to develop evidence-based standard testing methods and enforce the standards for product qualification during procurement. The committee shall consist of experts including AT users, development practitioners, service providers, production, and quality assurance and manufacturing. A strategic plan can be drafted to develop and implement the CLASP-ISWP model for AT products in the country after a thorough review of national AT policies, programs and services. The plan shall focus on developing a centralized system like CLASP or programs at partnering service providers and rehabilitation centers for collecting product performance data and developing a database. This data collection can provide information on usage, performance and failures of currently used AT devices in the region. Using this information, an AT product testing matrix can be developed similar to the ISWP approach (13). ATs like walkers, KAFO, tricycles and crutches that have been found to fail as frequently as once per month can be prioritized for test method development. In case wheelchairs are prioritized, wheelchair product testing resources disseminated by ISWP can be utilized for developing wheelchair testing capacity in LRS. Product testing results shall be iteratively correlated with the product failures and performance to inform the committee regarding improvements in testing methods. Test methods should be benchmarked for desired product performance in the community. Once test methods are fully developed, they can be proposed to national standard bodies for development and publication as a national standard. Testing outcomes shall be reported to manufacturers and providers for product quality improvements and development of new, appropriate AT designs. Testing outcomes and product performance data can be used to put together a Design Considerations document for ATs which can referred to by manufacturers, stakeholders and committees in other LRS.

In parallel with standards development, the body in charge of AT procurement may collaborate with the expert committee to develop a bidding process for ATs that are significantly needed in the context. The two-phase evaluation

process standardized by CLASP can be followed by the expert committee for screening products. AT testing standards developed by the committee and other testing standards (ISO, ISWP) can be suitably adopted in the screening process. Qualified AT products can be included on an online catalogue with product documentation, testing information, and product performance data with user feedback. This will promote informed decision-making during selection and procurement of appropriate locally manufactured and possibly, imported AT products. The CLASP-ISWP based AT provision model may benefit all the AT-sector stakeholders including users, product developers, procurement agencies, service providers, among others. It is important to note individuals who use AT have a protagonist role in this model as they serve in the expert committee and their experiences with the AT products will be the drivers of product quality improvement.

Challenges

This paper outlines a model for improving AT quality and procurement in LRS. The model's implementation can be challenging depending on existing systems, infrastructure and resources. The authors encourage national AT programs to adopt the proposed product procurement and quality model for their coordinated action to insure access to AT. This effort can be initiated with suitable support and funding from governmental and nongovernmental organizations.

Opportunities

Implementation of CLASP-ISWP model in LRS can open new possibilities like product innovation and competition. Since AT products will be reviewed against relevant testing standards and criteria, manufacturers in the AT sector will be compelled to innovate and compete to gain recognition in the marketplace. Local manufacturers and providers can team up with international manufacturers to gain competitive advantage by knowledge sharing on cost-effective, manufacturing practices, building products from local materials and context-appropriate parts, and sale of quality AT at affordable prices.

Conclusion:

There is an overwhelming need for appropriate, high-quality assistive technology globally and majority of this need is concentrated in LRS. Lack of regulations, funding and awareness has led to provision of inappropriate AT models through various procurement channels. To standardize procurement and quality of wheelchairs, USAID has supported two project initiatives – CLASP and ISWP. Coupling the CLASP-ISWP approaches can provide a model with a national strategic approach to streamline procurement and improve AT quality. Using this model proposed in the paper, a multidisciplinary expert committee can lead the development and adoption of evidence-based standard testing methods

appropriate for LRS, which can be used to qualify products during procurement. With suitable support from governmental and non-governmental organizations, the expert committee and AT users are encouraged to play a vital role in the implementation of the CLASP-ISWP model which has the potential to standardize procurement and quality of AT products in LRS.

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