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PROFESSIONAL OPINION

GLOBAL STANDARDS FOR PROSTHETICS AND ORTHOTICS

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Over the past decade, essential documents and agreements have emerged to help improve the lives of people with physical disabilities. These include Convention on the Rights of Persons with Disabilities (CRPD), ratified by more than 170 countries, and the World Health Organization (WHO) global disability action plan. While the principles in these broad agreements can be applied to people who would benefit from assistive technology, specific service standards are required to operationalize the CRPD and WHO objectives. Therefore, WHO, in partnership with the International Society for Prosthetics and Orthotics (ISPO) and the United States Agency for International Development (USAID), prepared global standards and an implementation manual to assist Member States in setting up, improving, or transforming their systems for delivering appropriate prosthetic and orthotic services.

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Prosthetics, Orthotics, Disabilities, World Health Organization.

The 60 new global “Standards for Prosthetics and Orthotics”¹ were developed to:

- Support countries work to “strengthen and extend rehabilitation, habilitation, assistive products, support services and community-based rehabilitation”², from the “WHO Global disability action plan”
- Achieve the eight recommended areas of rehabilitation in health systems from “Rehabilitation 2030: Call for action”³
- Achieve WHO GATE⁴ initiative goals, to improve access to high-quality, affordable assistive products globally
- Realize universal health coverage
- Support countries implementing CRPD, particularly Article 20 (Personal mobility) and Article 26 (habilitation and rehabilitation)

Universal health coverage is often confused with fully socialized healthcare. For the standards, the WHO definition applies: “ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they

need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.” This does not impose a health service funding or organizational model to achieve these goals.

These standards are for prosthetics and orthotics services, using a people centred care perspective. Therefore, the scope is beyond the prosthetist and orthotist, including devices that may be provided by other health care professionals with the right skills (i.e., physicians, nurses, physiotherapists, occupational therapists, pedorthotists, pedorthists, podiatrists). Internal prostheses are not covered (e.g., joint implants, dental prostheses). People-centred care includes psychosocial aspects that strengthens personal identity, enhances well-being, and recognizes the importance of social interactions.

The Standards are divided into four sections: policy, products (prostheses, orthoses), personnel, provision of services. *Challenges* are addressed in the standards and implementation manual:

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Policy

- Absence of policies and national plans for prosthetics and orthotics, rehabilitation, and assistive technology in most countries
- Lack of awareness and understanding about the role, purpose, and benefits of prosthetics and orthotics services
- Limited funding, with services frequently not included in national health and social insurance systems
- Limited data on needs for these services, making it difficult to understand the practical and financial requirements of providing such services for all

Products

- Limited availability of appropriate products in many countries
- High price of high-quality prostheses and orthoses
 - Even low-cost alternatives may be perceived as expensive, particularly in low- and middle-income countries
- Lack of national product standards in many countries, often resulting in devices that do not meet acceptable safety standards
- Limited evidence of the effectiveness and cost-effectiveness of products, technologies, and working methods

Personnel

- Lack of qualified personnel, reducing the quality and quantity of services
- Available personnel are usually found in large cities
- Limited access to schools and training opportunities for prosthetics and orthotics

Provision of Services

- Unequal service provision, with services are frequently available only in capital and other large cities and not to poor, isolated populations in rural areas
- Services for the poor are usually provided by charities and some Government institutions, which may offer poor quality products, while rich populations are frequently served by private clinics
- Prosthetics and orthotics services are frequently perceived as an expense rather than an investment

POLICY (15 STANDARDS)

Governments are encouraged to take a lead role in bringing stakeholders together and developing a national approach for prosthetics and orthotics services, moving beyond policy to include planning, implementation, and monitoring. An interesting standard (S3) recommends a national prosthetics and orthotics committee or similar entity, which would benefit both high and low-income countries, leading to a national guiding framework (S4). Regulation is also recommended (S5), which is typically not the situation for prosthetics and orthotics (i.e., typically certification, which does not have the same legal status, or no legal status). The need to monitor and have international sharing of experience, data, and research is recognized as essential for advancing services globally. Standards S13-S14 specifically address the need for data to enable decision-making.

Cost and funding of prosthetics and orthotics are addressed in standards S9 to S12. The need to have prosthetics and orthotics services considered “like other health interventions” is critical to achieve appropriate funding, and to enable cost-related factors that enable broad access. For example, why is prosthetic and orthotic funding considered differently from hip and knee replacement funding?

PRODUCTS (9 STANDARDS)

This important section addresses prosthetic and orthotic products, which is the most visible aspect of prosthetic and orthotic care. Standards S16-S18 include the availability and range of devices available in the local region and standards S19-S20 relate to components and materials. The ongoing discussion about the value of reusing components leads to the recommendation for regulation by a designated authority or “expert group” with no conflicts of interest, which would include issues such as black markets and resale as new, and quality control with documentation. The quality control and documentation aspects for reuse is often neglected or is handled on the organizational or business level instead applying broader requirements for audited documentation.

Technical standards (S21-S22) are important for national and international (International Organization for Standardization (ISO), etc.) bodies to ensure sufficient products quality and safety for consumers. National regulation of prosthetic and orthotic products, components, and materials is a step beyond most country’s approach, where

minimal requirements are in place for this medical device category and nothing is in place for the complete device.

Research related standards (S23-S24) include the need to develop affordable prosthetic and orthotic products that are cost-effective, of good quality, and context appropriate; which is different from trying to make the least expensive device, with subsequent lower quality. These research standards are related to the policy standards for data and sharing knowledge.

PERSONNEL (12 STANDARDS)

The personnel standards recognized the importance of having appropriate trained and competent professionals, within a multidisciplinary team for complex cases, provide prosthetic and orthotic care. Training should not only be aligned nationally but also with international education standards. Continuing professional development is considered compulsory. To meet this need, widely accessible learning opportunities will need to be developed, and continually updated, to match the pace of assistive technology advancement.

Workforce planning (S31-S33) should not only deal with recruiting and retaining appropriate service providers but should recognize “all the disciplines required in prosthetics and orthotics services at all levels”. This approach moves beyond the simple training of prosthetists and orthotists to involving national stakeholders to ensure a workforce that has local context and can be made available (i.e., flexible workforce that adapts to changing conditions). This flexibility remains a challenge in most regions.

The standards for professional regulation and recognition deal with accountability and career structure. As the world moves to address global assistive technology issues (fitting 1 billion people in need), maintaining quality services will require health care professionals, associates, and technical personnel with clearly define roles and responsibilities. The alignment of prosthetists and orthotists within the scope of health professionals remains problematic and requires global effort to achieve appropriate positioning. This is critical for the evolving “associate” level practitioner where responsibilities could be expected to vary depending on the country and circumstance (i.e., larger scope in developing or crisis area).

PROVISION OF SERVICES (24 STANDARDS)

To achieve user-centred service delivery, the standards endeavour to promote services where “every user with a physical impairment or functional limitation can make informed decisions about her or his care, services, and service providers”; and “services are planned from the perspective of the individual user and respond to her or his needs and preferences, respecting their dignity, choices and rights.” The standards recommend documented policy to safeguard the rights of users, involving service users and their representatives at all levels, and providing choice for service providers and technology.

To achieve this vision, service delivery models should facilitate accessibility (S40), be part of the health system (S41,S45,S46), be delivered as a 3-tier system (S42), and consider maintenance and repair as part of the service (S43). Standards 47 and 48 address the service environment, recommending service provision in a user-friendly, barrier-free, safe, clinical environment that is properly equipped.

Service delivery is divided into four steps (assessment, fabrication and fitting, user training and product delivery, follow-up) that are covered in nine standards. Evidence based practice and care documentation are essential. User centre care principles are included throughout these four steps. Quality management approaches should be used, with annual and long-term planning supported by continuous monitoring of performance indicators.

Consideration prostheses and orthoses in disaster conditions (S44) is an interesting standard since the attention to services may not be included in many country’s disaster plans, especially since prosthetic and orthotic care is a long-term (lifetime) service requirement and thereby requires different planning considerations than acute care needs.

IMPLEMENTATION

The accompanying Implementation Manual provides detailed ideas and examples of how each standard can be operationalized. Of these, the following items are of particular interest:

Stakeholders: A broad approach should be considered when engaging people and groups. A list of stakeholders and their roles are provided, and

can be used to engage with these people or groups (i.e., ask why a group is not engaged when they are identified in the standards)

National approach: In most countries, at least one of the standards or implementation ideas is likely lacking; for example, having a government supported prosthetic and orthotic committee with a 5–10-year plan that is specific, measurable, achievable, realistic, and timely

A national audit of how each country currently adheres to the standard, with global reporting to allow for inter-country benchmarking, is an important step to understand deficiencies and successes. This information will empower country and global regions to advocate and achieve positive change for prosthetic and orthotic services

Data and Evidence: Implementing positive change requires solid evidence. With the many players involved with provision (public, private, hospital, military, etc.) and funding, new strategies are required to obtain quantitative evidence on costs and economic impact; best practices; products; human resources; unmet needs

Research: The need for continued research is apparent, but the standards reiterate the need for global collaboration (project formulation, multi-country studies, etc.) and sharing to make the best use of this research, thereby expanding the evidence base on prosthetics and orthotics services. These global factors include identifying and standardizing research questions, using standardized tools, increasing research-related investment, and broadening the range of experts involved with prosthetic and orthotic related research (e.g., health economists, human rights experts, policy analysts, etc.).

These WHO global standards for prosthetic and orthotic services are important for enhancing understanding of the expectation for appropriate care, regardless of the person's location or economic status. As with any standards, success is directly related to how they are applied. With local, national, and international efforts, positive change can be realized to deal with the current state of only 1 in 10 people in need having access to assistive products, thereby "helping people to become more active and to live healthy, productive, independent, dignified lives and to participate in education, the labour market and social life".

REFERENCES

1. WHO standards for prosthetics and orthotics. Geneva: World Health Organization; 2017 (<http://www.who.int/rehabilitation/prosthetics-and-orthotics-standards/en/>, accessed 31 October 2018).
2. WHO global disability action plan 2014–2021. Better health for all people with disability. Geneva: World Health Organization; 2015 (<http://www.who.int/disabilities/actionplan/en/>, accessed 31 October 2018).
3. Rehabilitation 2030. A call for action. Geneva: World Health Organization; 2017 (<http://www.who.int/disabilities/care/rehab-2030/en/>, accessed 31 October 2018).
4. Global cooperation on assistive technology (GATE). Geneva: World Health Organization; 2016 (http://www.who.int/phi/implementation/assistive_technology/phi_gate/en/, accessed 31 October 2018).

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Terry J. Supan, is President and CEO of Supan Prosthetic Orthotic Consultations. He is a Clinical Professor (Retired) at Southern Illinois University School of Medicine and a former Chair of the Illinois Orthotic, Prosthetic and Pedorthic Licensure Board. He is a licensed and board certified orthotist and prosthetist that specialized in upper limb amputations, cerebral palsy, scoliosis, polio, stroke, and other rehabilitation for persons with physical disabilities. He is an internationally known speaker in those areas as well as lower



limb prosthetics; biomechanics/gait analysis; prosthetic/orthotic education; state O&P practice acts; and governmental regulations. Mr. Supan served as the President of the American Academy of Orthotists and Prosthetists' (AAOP) in 1990 -1991. On March 22nd, 2012 the Academy bestowed the Titus-Ferguson Lifetime Achievement Award on Mr. Supan. He is a Fellow of both the AAOP and the ISPO. In June of 2015 he was appointed to the International Society for Prosthetics and Orthotics Executive Board and serves as the Treasurer of ISPO. He was re-elected as ISPO Treasurer in 2017 and will serve in that capacity until 2019.

Marlo Ortiz

Marlo Ortiz graduated as an Engineer in 1977 from University of Guadalajara, Mexico and later undertook courses in Prosthetics and Orthotics until 1979, when he began to practice as a certified clinical prosthetist (Barra Mexicana de Certificacion en Ortesis y Protesis A.C.). He was recipient of the "Clinical Creativity" Prize presented at the 2005 AAOP meeting in Orlando and "Blatchford Prize" for Best "Prosthetic Technology" at the ISPO 2007 World Congress in Vancouver. Marlo Ortiz is an international speaker with O&P presentations at meetings in many countries for over 20 years. He is also National Coordinator of Uniting Frontiers Regional Board, International Representative of ISPO Mexico National Member Society, and member of the Executive Board of ISPO International.

