World Health Organization

STANDARDS FOR PROSTHETICS AND ORTHOTICS

Part 1: STANDARDS

USAID FROM THE AMERICAN PEOPLE

ISPO

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WHO standards for prosthetics and orthotics

Contents: Part 1. Standards; Part 2. Implementation manual

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Abbreviations and acronyms

CPD continuing professional development

CRPD Convention on the Rights of Persons with Disabilities

GATE Global Cooperation on Assistive Technology

ISO International Organization for Standardization

ISPO International Society for Prosthetics and Orthotics

SDG Sustainable Development Goal

USAID United States Agency for International Development

Definitions

Appropriate technology
Systems that provide fit and alignment that suit the needs of the individual and can be sustained by the country at the lowest price. Proper fit and alignment should be based on sound biomechanical principles *(1)*.

Assistive products
Any external product (including devices, equipment, instruments and software), specially produced or generally available, the primary purpose of which is to maintain or improve an individual's functioning and independence and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions *(2)*.

Assistive technology
Organized knowledge and skills related to assistive products, including systems and services. Assistive technology is a subset of health technology *(2)*.

Disability
An umbrella term for impairments, limitations of activity and restrictions on participation resulting from the interaction between people with health conditions and the environmental barriers they encounter *(3)*.

Health condition
An umbrella term for disease (acute and chronic), disorder, injury or trauma. Health conditions may also include circumstances such as pregnancy, ageing, stress, congenital anomaly or genetic predisposition *(4)*.

Impairment
Loss of or abnormality in a body structure or physiological function (including mental function), where "abnormality" is used to mean significant variation from established statistical norms *(4)*.

Multidisciplinary rehabilitation team
In the context of this document, rehabilitation provided by two or more different types of rehabilitation professional.

Occupational therapy
Techniques to enable people to participate in the activities of everyday life by enhancing their ability to engage in the occupations they want, need or are expected to do or by modifying the occupation or the environment to support their occupational engagement *(5)*.

Orthosis, orthotic device or product
Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems *(6)*.

Orthotics
Science and art of treating people by the use of orthoses *(6)*.

Orthotist
A person who has completed an approved course of education and training and is authorized by an appropriate national authority to design, measure and fit orthoses *(6)*.

People-centred care
An approach to care in which the perspectives of individuals, caregivers, families and communities are consciously adopted so that people are participants in and beneficiaries of trusted health systems that respond to their needs and preferences in humane, holistic ways. People-centred care also requires that people have the education and support they require to make decisions and participate in their own care. It is organized around the health needs and expectations of people rather than diseases *(7)*.

People with disability
People who have long-term physical, mental, intellectual or sensory impairments, which, when they meet various barriers, may hinder their full, effective participation in society on an equal basis with others *(8)*.

Physiotherapy (sometimes referred to as physical therapy)
Services to individuals and populations to develop, maintain and restore maximum movement and functional ability throughout the lifespan, including in circumstances where movement and function are threatened by ageing, injury, pain, disease, disorders, conditions or environmental factors. Functional movement is central to being healthy *(9)*.

Prosthesis, prosthetic device or product
Externally applied device used to replace wholly or partly an absent or deficient limb segment *(6)*.

Prosthetics
Science and art of treating people by the use of prostheses *(6)*.

Prosthetist
Person who has completed an approved course of education and training and is authorized by an appropriate national authority to design, measure and fit prostheses *(6)*.

Prosthetist and orthotist

Person who has completed an approved course of education and training and is authorized by an appropriate national authority to design, measure and fit prostheses and orthoses *(6)*. In the context of this document, this term is also used to refer collectively to prosthetists, orthotists and prosthetists and orthotists.

Rehabilitation

A set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment *(10)*. (See also Health condition.)

Universal health coverage

Universal health coverage is defined as "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" *(11)*.

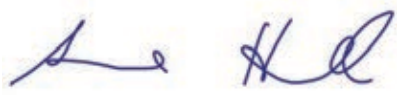
Preface

Prostheses (artificial legs and hands) and orthoses (braces and splints) enable people with physical impairments or functional limitations to live healthy, productive, independent, dignified lives and to participate in education, the labour market and social life. The use of prostheses or orthoses can reduce the need for formal health care, support services, long-term care and caregivers. Without access to prostheses or orthoses, people who need them are often excluded, isolated and locked into poverty, which increases the burden of morbidity and disability.

The Convention on the Rights of Persons with Disabilities (CRPD) states that Member States are responsible for taking effective measures to ensure personal mobility for the greatest possible independence of people with disabilities. They also have a corresponding responsibility to promote and ensure the availability of and access to mobility aids, devices and assistive technologies, including prostheses and orthoses. Since 2006, more than 170 countries have ratified the CRPD and are therefore obliged to ensure access to affordable, high-quality assistive products, including prostheses and orthoses.

WHO estimates that, today, only 1 in 10 people in need has access to assistive products, including prostheses and orthoses, because of their high cost and because of lack of awareness, availability, trained personnel, policy and financing. Hence, WHO is coordinating a global initiative, "Global cooperation on assistive technology" (GATE), to improve access to high-quality, affordable assistive products. WHO's global disability action plan for 2014–2021 and the subsequent publication *Rehabilitation in health systems* request Member States to develop financing and procurement policies to ensure that assistive products, including prostheses and orthoses, are available to everyone who needs them.

To improve access to prosthetics and orthotics services, WHO, in partnership with the International Society for Prosthetics and Orthotics (ISPO) and the United States Agency for International Development (USAID), has prepared global standards and an implementation manual to assist Member States in setting up, improving or transforming their systems for delivering these services. One aim of the document is to ensure that prosthetics and orthotics services are integrated into health services and systems, as they are often provided at the same time as other health services. WHO believes that this document will promote greater access to these services globally, as another step towards strengthening universal health coverage and achieving the Sustainable Development Goals (SDGs).



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Executive summary

This document provides a set of standards and a manual for implementation to support countries in developing or improving high-quality, affordable prosthetics and orthotics services. It brings promise, by ensuring that everyone in need, everywhere, has access to prostheses and orthoses: that no one is left behind. Its aim is to ensure that prosthetics and orthotics services are people-centred and responsive to every individual's personal and environmental needs.

Implementation of these standards will support Member States in fulfilling their obligations under the CRPD *(8)* and in meeting the SDGs *(12)*, in particular Goal 3: Ensure healthy lives and promote well-being for all at all ages. With these standards, any government can develop national policies, plans and programmes for prosthetics and orthotics services of the highest standard.

This document has two parts: the standards and an implementation manual. Both parts cover four areas of the health system:

- policy (governance, financing and information);
- products (prostheses and orthoses);
- personnel (workforce); and
- provision of services.

The **Introduction** outlines the scope and purpose of the document and describes the importance of ensuring access to prosthetics and orthotics services for people with physical impairments or functional limitations in order to respect their human rights and allow them to achieve mobility and dexterity and participate in society. According to the CRPD, facilitating the access of people with disabilities to mobility aids and assistive devices and technologies is a State obligation *(8)*. The section also recalls that only 5–15% of those who could benefit from assistive products, including prostheses and orthoses, have access *(13)*. Critical challenges in developing prosthetics and orthotics services are identified, such as lack of dedicated policies and national strategic plans; a general lack of understanding about the role, purpose and benefits of these services; limited funding; and the relatively high cost of service delivery.

Part 1. Standards for prosthetics and orthotics

Area 1. Policy points out the responsibility of Member States to promote the availability and use of prostheses and orthoses at a cost that is affordable to users or the State. It recalls that governments should assume a leading role in or delegate responsibility for the governance of nationwide prosthetics and orthotics services and should involve a range of stakeholders in planning, developing and monitoring services. A guiding framework, consisting of legal acts, policies, strategic plans, standards, rules and regulations, should be in place to guide the

design of affordable, accessible, effective, efficient, safe services of high quality. The section states that funding of prosthetics and orthotics services must be included in moving towards universal health coverage. Access to prostheses and orthoses can be greatly increased by appropriate financing, especially through national health and/or social insurance. The argument is made that money spent on these services is not an expense but an investment that generates both social and economic returns.

Area 2. Products emphasizes that prosthetic and orthotic products and working methods should be appropriate to the setting in which the products are fabricated, fitted, used and funded. Establishment of a national list of priority products helps to create public awareness, mobilize resources, guide product development and procurement and stimulate competition to make the products available at an affordable cost. The section proposes that prosthetic and orthotic materials and components and the tools, machines and equipment used in the services be exempt from import taxes and customs fees in order to ensure that they are affordable and accessible. It urges national and international stakeholders, including the private prosthetics and orthotics industry, to develop alternative, affordable products made of cost–effective, good-quality, context-appropriate components.

Area 3. Personnel identifies the requirements to be considered in planning, developing and promoting professional recognition of the workforce. It stresses the importance of training various types of prosthetics and orthotics personnel to meet nationwide demand and urges the promulgation of State regulations to ensure that service users are protected from malpractice and poor-quality services. Prosthetics and orthotics clinicians should be recognized as independent health professionals with a distinct professional title, profile and job description. The section states the importance of a multidisciplinary team approach in prosthetics and orthotics, especially for people with severe or complex physical impairments.

Area 4. Provision of services emphasizes the importance of people- or user-centred prosthetics and orthotics services. Users must be regarded as equal members of the treatment team and be given the necessary information to empower them to make decisions about their care and final selection of a product. They should be consulted and involved in policy development and in planning, implementing, monitoring and evaluating services. The section positions prosthetics and orthotics services as an integral part of health services, closely related to medical, surgical and rehabilitation services. It raises the importance of coordination with other sectors, such as labour, social welfare and education, for overall health and rehabilitation outcomes. The section outlines standards for referral, service delivery and service unit management.

The section entitled "The way forward" states that implementing the standards should involve various stakeholders. Eight steps are identified in setting up or improving a national prosthetics and orthotics service and implementing the standards. The section recommends that Member States adapt the 60 standards to suit their contexts, giving priority to those that must be implemented to safeguard users' rights and safety and to ensure quality and performance. In countries with limited resources, particularly those requiring technical

assistance, technology transfer or capacity-building, the development or improvement of national prosthetics and orthotics services can be supported by the international cooperation framework described in CRPD Article 32. The section ends with priority research agendas and research questions and urges international support for Member States to generate more evidence to promote the prosthetics and orthotics sector globally.

Part 2. Implementation manual

The structure of the implementation manual is similar to that of Part 1 on standards but provides details to assist policy-makers and health care programme managers, particularly of rehabilitation services, in planning, implementing, managing and further developing prosthetics and orthotics services to meet the standards. It elaborates on the standards, describing "what, why, how, who and when".

The manual can be used as a reference document and to stimulate discussion at national and service delivery levels during the development of strategic plans, tools and methods for strengthening prosthetics and orthotics service delivery, area-by-area, as necessary in each context. This will ensure that users of prosthetics and orthotics receive the best-quality services and products, contributing to the overall aim of optimal functioning, full participation and inclusion of every individual in society.

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About this document

Purpose

Part 1 of this document presents a set of standards for countries to use in developing or strengthening essential, affordable, accessible, effective, efficient, safe prosthetics and orthotics services of high quality. Part 2 of the document is a manual for operationalizing the standards.

The standards are aligned with the United Nations CRPD *(8)*. Adoption of these standards will support governments in fulfilling their obligation to implement the CRPD and in meeting the SDGs, in particular Goal 3: Ensure healthy lives and promote well-being for all at all ages *(12)*. Using these standards, any government can develop national policies, plans and programmes for the highest standard of provision of prosthetics and orthotics services.

Aims

- Support countries in implementing objective two of the *WHO Global disability action plan 2014–2021 (14)*, to strengthen and extend rehabilitation, habilitation, assistive products, support services and community-based rehabilitation *(14, 15)*.
- Support stakeholders in their work to achieve the eight recommended areas of rehabilitation in health systems and the subsequent *Rehabilitation 2030: Call for action* for coordinated, concerted global action towards strengthening rehabilitation in health systems *(16)*.
- Contribute to achieving the goal of WHO's GATE initiative (see Box 1), which is to improve access to high-quality, affordable assistive products globally *(17-19)*.
- Contribute to realizing universal health coverage to ensure that all people can use the promotive, preventive, curative, rehabilitative, assistive and palliative health services they need, which are of sufficient quality to be effective, and also ensuring that use of these services does not impose financial hardship on the user *(11)*.
- Support countries in implementing the CRPD, in particular Article 20 (Personal mobility), which includes facilitating access to high-quality mobility aids, devices and assistive technologies, and Article 26 (Habilitation and rehabilitation), which calls for the organization, strengthening and extension of comprehensive habilitation and rehabilitation services and programmes *(8)*.

Box 1. Global Cooperation on Assistive Technology (GATE)

The aim of WHO's GATE initiative is to remove barriers to inclusion and participation in society by improving the availability and affordability of assistive products, including prostheses and orthoses, for everyone, everywhere.

Today, only 5–15% of the population in need has access to assistive products *(20)*, i.e. products for people with impaired mobility, sight, hearing, speech or cognition. Without access to such products, many individuals in need are confined to their homes and live dependent, excluded lives, increasing the impact of the impairment and disability on the person, family and society. The GATE initiative is designed to address this huge unmet need and to realize Article 20 (Personal mobility) and Article 32 (International cooperation) of the CRPD *(8)*.

To achieve its main objective, GATE recently published a list of priority assistive products *(2)*, on which prostheses and orthoses are identified as essential.

Scope

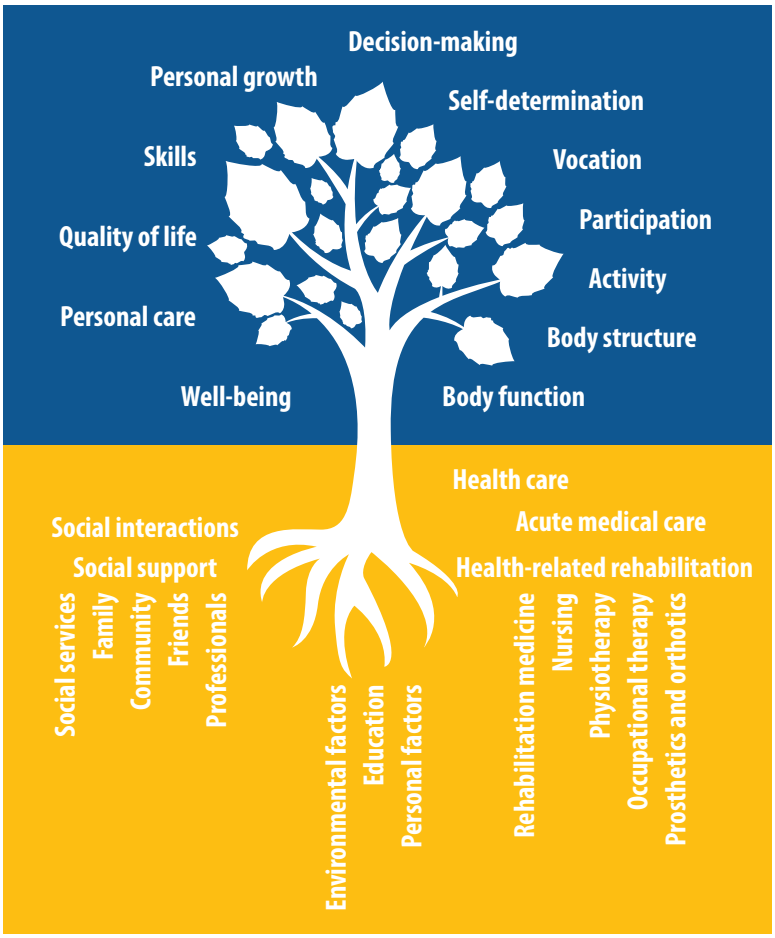
The document covers the services provided by prosthetics and orthotics personnel, particularly prosthetists and orthotists. Certain types of orthosis may be provided by other health care professionals who have the right skills, such as physicians, nurses, physiotherapists, occupational therapists, pedorthotists, pedorthists and podiatrists. Where relevant, the standards should also apply to services provided by these professionals. Internal prostheses, such as joint replacement implants and dental prostheses, are not covered.

To guide Member States in improving access to prostheses and orthoses, the document presents 60 standards that need to be in place to safeguard user rights, safety, quality and performance of service systems and products. The standards defined are global and are neither country-specific nor exhaustive. Countries can prepare more detailed standards in all the areas covered, particularly for technical work in service delivery. National and international stakeholders in prosthetics and orthotics are encouraged to use this document in cooperating and collaborating in the development of technical resources.

People-centred care

This document places the prosthetics and orthotics service user at the centre of the establishment, development and maintenance of services of the highest possible quality. It promotes services that are responsive, effective and efficient and can maximize the number of people assisted. People-centred care strengthens personal identity, leading to enhanced well-being. Social interactions with family, friends and the community and educational and health care are all important. Such support helps people to flourish and participate in activities that contribute to an optimum quality of both personal and social life (Fig. 1).

Fig. 1. People-centred care and benefits



Target readership

This document is intended primarily for policy-makers and programme managers responsible for health care, welfare, rehabilitation and prosthetics and orthotics services. The standards and other information are also applicable to a broad range of other professionals involved in prosthetics and orthotics, such as service providers, professional organizations, user groups, training institutions, donor agencies, civil society, and nongovernmental and international organizations.

Structure

Adhering to the building blocks of WHO's concept of health systems strengthening *(21, 22)*, this document is relevant for four key areas of health systems, presented in four sections: policy (including leadership, governance, financing and information), products (prostheses and orthoses), personnel and provision of services (Fig. 2).

Fig. 2. The four key areas of health systems addressed by the standards

Part 2 of the document has a similar structure and covers the same four key areas of the health system as Part 1, providing more detailed explanations of planning, implementing, managing and further developing services and systems for prosthetics and orthotics. The two parts are complementary, with a coding system to allow the reader to find more information on a topic in the implementation manual. For example, "1A. Stakeholders and their roles" refers the reader to section 1A of the implementation manual.

Links with other WHO documents

This document was written in the light of the WHO *World report on disability (3)*. It reflects the WHO publication on health systems strengthening and connects with universal health coverage *(22)*. It updates the *Guidelines for training personnel in developing countries for prosthetics and orthotics services (23)*, going beyond training of personnel and developing countries. It also complements the *Guidelines on the provision of manual wheelchairs in less-resourced settings (24)*, *Community-based rehabilitation: CBR guidelines (20)* and *Rehabilitation in health systems (10)*.

Preparation of the standards

The standards were prepared in a four-stage, collaborative process (Fig. 3) involving two departments of WHO: Essential Medicines and Health Products and Management of Non-communicable Diseases, Disability, Violence and Injury Prevention, as well as WHO regional and country offices.

Fig. 3. Collaborative process

In consultation with the WHO regional offices, three groups were formed to prepare the standards: the WHO Steering Group, the Standards Development Group and the External Review Group.

The WHO Steering Group selected members for the Standards Development Group and the External Review Group, drafted questions on the basis of the problem, intervention or indicator, comparison and outcome of interest ("PICO") and oversaw evidence retrieval and the writing and finalization of the standards.

Two systematic reviews of the literature were commissioned to answer the PICO questions and retrieve evidence from the databases of medical, health and policy-related publications. The objective of the first was to find information on the effectiveness and cost–effectiveness of prosthetics and orthotics services, and the second was to find which skills are required to deliver and manage high-quality services (standards and models). Both review teams included a wider network of reviewers. Representatives of the review teams joined a consensus meeting of the Standards Development Group in Bangkok, Thailand, in November 2015, where they presented their findings. The meeting determined the scope of the standards and set directions for the development of the document.

WHO commissioned two authors to write the document in close consultation with representatives of the WHO Steering Group. The Standards Development Group reviewed two drafts, chose and ranked standards, appraised the evidence on which the standards were

based, provided examples of best practices and submitted content for some of the sections. The External Review Group was consulted in the second review. All consultation responses, including consensus outcomes, expert opinions and evidence, were taken into account in formulating the final standards statements and content.

Declarations of interests

The management of conflicts of interest was a key priority throughout the development process of these standards. The competing interests that may occur in health care result in the potential for conflicts of interest and may lead to biased generation or assessment of evidence and to misinformed health care policies. WHO has stringent policies for avoiding conflict of interest, particularly in the development of official guidance documents that affect health care. Hence, each author and meeting participant was asked to declare any potential area of conflict. All members of the Standards Development Group and the External Review Group signed the Declaration of Conflict of Interests for WHO Experts. Following WHO standard practice to enhance its management of conflicts of interest, and strengthen public trust and transparency in connection with WHO meetings or products involving the provision of technical/normative advice, the names and brief biographies of individuals of the Standards Development Group were published on the WHO website for public notice and comment *(25)*. After analysis of each declaration of interest, it was concluded that there were no conflicts of interest that would exclude any individual from participating in the development process.

Two lead authors were selected following the WHO Request for Proposals bidding process. The process of Declaration of Conflict of Interests was appropriately followed. Author one, Anders Eklund, previously worked for WHO and currently serves as a freelance consultant. Sandra Sexton, previously director of the National Centre for Prosthetics and Orthotics, University of Strathclyde, and then grant manager of ISPO served as second author. WHO colleagues involved in the development process of these standards were also deemed not to have any direct conflict of interest.

Implementation of standards

The 60 standards presented in this document are intended to stimulate Member States to establish and maintain appropriate systems and infrastructure for the provision of high-quality prosthetics and orthotics services. This depends on the financial, human and other resources that can be mobilized in each country; some will find implementation more challenging than others, and, in many cases, full implementation will take longer. Nevertheless, although each standard may not immediately be realized, it will serve as a goal to be reached and a guide to setting benchmarks and finding resources to achieve the goal. All Member States are expected to take gradual steps towards full implementation.

Effective implementation of the standards requires joint action among all relevant national stakeholders, including users and their representatives or organizations, government ministries, service providers, nongovernmental and professional organizations and donor agencies.

It is suggested that implementation of the standards follow four steps:

Step 1: Compare national prosthetics and orthotics systems and services with the complete set of standards (Annex 1) to derive a baseline against which to monitor future developments.

Step 2: Identify priorities for action, guided by Part 2 of this document.

Step 3: Prepare a 5–10-year national strategic plan, with clear benchmarks for implementation in each area (policy, products, personnel and provision of services).

Step 4: Conduct annual and mid-term evaluations by comparisons with the benchmarks to determine progress, and update the plan as needed.

Box 2. Jaya and Jay's story, India

In 1980, sister and brother Jaya (age 5) and Jay (age 3) contracted the polio virus and became paralysed in their legs and spines within a week of one another, the entire family's life changed in an instant: a happy family was immediately labelled a "cursed" family. Household expenditure soared in the search for a possible cure or at least rehabilitation. Their parents stayed firm against the stigma and prejudices and decided that their children would be educated like other children. Getting children with disabilities into a regular school was not easy at that time, and so they went to a school run by the Association of People with Disabilities in Bangalore. There, they had their first experience of physiotherapy and orthoses, which consisted of heavy metal braces with black boots. They were happy at the school, but it went only up to 7th grade. To continue their education, they went to a regular school, where the environment was hostile. They quickly learnt tricks to cope with the attitudinal barriers and also with the inaccessible physical environment, especially toilets. Minds of steel, family support and using metal orthoses helped Jaya and Jay to complete their schooling.

In 1997, Jaya went to Mobility India for a pair of light-weight plastic orthoses – the first time she had a pair of orthoses without a pair of men's black boots. When the orthoses were delivered, she was offered a job as secretary in Mobility India. A few years later, Jay followed the same path, with new orthoses and a job. Both Jaya and Jay married, and Jaya is now the mother of a daughter and Jay the father of two children. Jaya and Jay are role models and examples of what a difference good-quality orthoses can make. Society's attitude towards a cursed family changed, and the family is a happy one once again.

Dissemination

This document will be disseminated to a broad network of stakeholders, including WHO regional and country offices, ministries of health and other relevant government ministries, WHO collaborating partners, including nongovernmental and international organizations,

professional and research networks, other United Nations agencies, donor agencies and disabled people's organizations. The document will also be disseminated through the networks of ISPO and USAID, especially their national member societies and country offices. Dissemination will be facilitated by publication of summaries of the document in relevant journals and promotion though media initiatives.

Review and updating of the document

It is anticipated that the standards proposed in this document will remain valid until 2022. The departments of Essential Medicines and Health Products and of Management of Noncommunicable Deceases, Disability, Violence and Injury Prevention at WHO headquarters in Geneva will be responsible for initiating a review of the standards at that time. If, however, in the next five years, there are significant changes in the evidence base that have implications for the standards, the review will be undertaken sooner.

Introduction

Prostheses and orthoses

Prostheses and orthoses are externally applied devices and products used to assist people with physical impairments or functional limitations, to improve their functioning and increase their potential to live healthy, productive, independent, dignified lives. A prosthesis is an externally applied device used to replace wholly or partly an absent or deficient limb segment (arm or leg) *(6)*. Common examples are artificial legs and arms. An orthosis is an externally applied device used to support or modify the structural and functional characteristics of the neuromuscular and skeletal systems (such as arms, legs and the spine) *(6)*. Common examples are braces, splints and supports.

Prostheses and orthoses have various purposes, including to improve the mobility, dexterity or functioning of the user; alleviate pain; restore cosmesis; protect joints; prevent and correct deformities; and prevent secondary impairments. Most prostheses and orthoses are required for long-term use and others for limited periods. Prosthetic and orthotic products are also mobility devices, which include wheelchairs and walking aids such as crutches and walking frames. Mobility devices, in turn, are broadly classified as assistive products, which also include products for improving vision, hearing, communication, cognition and environment (Fig. 4). In health care regulations, prosthetic and orthotic products are most appropriately defined as health products.

Fig. 4. Family of assistive products

Prosthetics and orthotics

Prosthetics is a specialty within the medical and health care field concerned with the research and development, design, manufacture and application of prostheses. Similarly, orthotics is a discipline concerned with orthoses. Prosthetics and orthotics often comprise similar steps in service delivery and similar tools, equipment and working methods and are therefore usually taught, promoted and practised together. "Prosthetics and orthotics" is the umbrella term for the science, technology, education and application of prostheses and orthoses.

Prosthetics and orthotics services

"Prosthetics and orthotics services" is an umbrella term for the combination of inputs, such as policy (financing), products (components and material), personnel, required to deliver the appropriate prostheses, orthoses and related therapy *(26)*. As in any health service, improving access to and the coverage and quality of prosthetics and orthotics services depends on the availability of resources, the organization and management of services.

Prosthetics and orthotics services provide comprehensive care with preventive, promotive, assistive and rehabilitative interventions. They usually involve assessment of potential users and a treatment plan, including the design, manufacture, fitting and delivery of prostheses and orthoses.

Prosthetics and orthotics services within health care

Prosthetics and orthotics services are part of health care and are often included in rehabilitation services. Like other health services, their aim is to optimize users' health and well-being. The interventions are usually part of the health care continuum, such as providing therapeutic or protective footwear in the treatment of a diabetic or neuropathic foot, fitting a prosthesis after amputation or provision of an orthosis to support a paralysed limb after a stroke. Timely prosthetics and orthotics service provision is important to restore functioning and to prevent secondary deformities.

With other interventions, such as education, skills training, job coaching, placement and social support, prosthetics, orthotics and rehabilitation services contribute towards the overall aim of optimal functioning and hence full participation and inclusion in society. All interventions are important to achieve this goal (Fig. 5).

Fig. 5. Connecting with other interventions

Users

Users of prosthetics and orthotics services are people in all walks of life who have physical impairments or functional limitations, due, for example, to:

- noncommunicable diseases, such as diabetes, stroke, cancer and peripheral vascular disease;
- communicable diseases, such as tuberculosis, poliomyelitis and Buruli ulcers;
- injuries due to falls, road traffic and industrial accidents, natural disasters, war and conflicts;
- degenerative changes in the spine, hip, knee, foot, ankle or upper limbs;
- congenital anomalies or limb deficiencies; and
- cerebral palsy.

Most users have long-term chronic health conditions, such as limb amputation, limb paralysis, spinal cord injury or structural deformities, and therefore a lifelong need for health care, including prosthetics and orthotics. Others may require medium-term provision, such as in the management of adolescent scoliosis until bone maturity, or short-term provision, for example to support healing after a traumatic injury or fracture.

Many users require a continuum of care that evolves during their lifetime. Prostheses and orthoses must be repaired, adjusted, modified and replaced at intervals that depend on environmental factors, user activity and physiological changes. A 10-year-old child whose lower limb was amputated, for example, is likely to require 25–30 prostheses over the course of their life *(26)*. Service users should have the right to be treated by the same clinician for a substantial part of their life (when possible), because of the complex psychosocial, physical and technical provider–user relationship.

Numbers required

Although the need for prosthetics and orthotics services can be assessed in various ways (see 1N of Part 2), precise, reliable figures are frequently not available for countries. It has been estimated, however, that 0.5% of any population globally requires prostheses and orthoses and rehabilitation treatment *(24)*. This estimate does not take into account local factors that may result in more impairments (such as conflict, many traffic injuries, highly prevalent disease) or fewer (due, for example, to successful prevention of accidents or good trauma care). Nevertheless, it gives an idea of the challenge countries are facing. The estimate of 0.5% of the world population would correspond to 35–40 million people globally who require prosthetics and orthotics services. At least two to four times more people attend services for orthotic treatment than for prosthetic treatment *(27)*.

Over the next few decades, the number of people requiring prosthetics and orthotics services is bound to rise because both the world's population and life expectancy are growing. As a larger proportion of the ageing population will be affected by disability *(28)*, the need for services will rise proportionally. The world is witnessing significant increases in musculoskeletal conditions *(29)* and noncommunicable diseases *(30)* such as diabetes *(31, 32)* (see example in Box 3) and stroke *(33, 34)*, which, if they continue, will greatly add to the need for prosthetics and orthotics. Thus, by the middle of this century, the proportion of the world's population that requires services is likely to be closer to 1%.

Box 3. The increase in noncommunicable diseases: diabetes

An estimated 415 million people were reported to have diabetes in 2015, and this figure is expected to rise to 642 million in 2040 *(32)*. As 60–70% of people with diabetes lose sensation in their feet, they are at risk for injury. Furthermore, 12–15% of people with diabetes will develop a foot ulcer *(35, 36)*, which increases their risks for infection, amputation or even premature death. Service users can reduce their risks, improve their healing rates and prevent amputation by following advice on foot care and using orthoses, including appropriate footwear *(37, 38)*.

Current access

Data on the needs and unmet needs for prosthetics and orthotics are lacking in most countries; several do not have prosthetics or orthotics service facilities. When they are available, facilities are usually located in capital or other large cities. The harsh reality in many countries is that only 5–15% of the people who could benefit from assistive products have access to them *(13)*, including prostheses and orthoses. Even in high-income countries, many people also struggle to access these services. Governments and stakeholders must collect data on needs and unmet needs to serve as a basis for the development of nationwide prosthetics and orthotics services and to monitor progress towards achieving the SDGs and meeting their obligations under the CRPD. In the absence of proper data, it may be wrongly assumed that needs are met if the demand for such services (the number of people who

actively seek assistance) is low. In many countries, the need for services may be considerably greater than the demand, as many people may not be aware of the services or cannot access them for various practical reasons, such as affordability and distance.

Benefits of prosthetics and orthotics services

Prosthetics and orthotics services have important benefits at various levels. Appropriate provision improves the functioning of people with physical impairments or functional limitations, which increases their mobility and functioning and helps them stay active and productive. This, in turn, increases their independence, self-determination, participation in society and well-being and helps them to lead longer, dignified lives of higher quality. For many users, prostheses and orthoses allow them to gain access to education and work. Prosthetics and orthotics services thereby contribute to removing barriers and integrating people with physical impairments or functional limitations into society and giving them equal opportunities, as is their right.

Prosthetics and orthotics services also generate significant economic benefits: for the users (who may work and earn an income), for their families and communities (as users require less care and assistance), for health services (as they help to accelerate recovery, shorten hospital stays and reduce the need for frequent medical help or re-admission), for society and for the country as a whole (as users become more independent and healthy, reducing health and welfare costs). These benefits are particularly tangible in poor populations, where prosthetics and orthotics can help people escape from extreme poverty.

These services can stimulate economic growth by enabling a more productive workforce and also by opening up markets and creating job opportunities for the production of prosthetic and orthotic components and service delivery. They are therefore an important economic investment (see 1F of Part 2). Not making such an investment has real negative effects: without access to high-quality prostheses or orthoses, people with physical impairments or functional limitations are at greater risk for exclusion, dependence, isolation and, ultimately, poverty, all of which entail great social and economic costs for families, society and the country.

Prosthetics and orthotics services as a precondition for ensuring respect for human rights

Access to prosthetics and orthotics services is essential for people with structural or functional limitations not only to achieve mobility and independence but also to enjoy their human rights in the same way as others in the community *(39)*. The CRPD states that facilitating access to mobility aids, assistive devices and technologies is a State obligation *(8)*. More than 170 countries have ratified the Convention, obliging them to ensure access for people in need to high-quality affordable prosthetics and orthotics services.

SDG 3 is to ensure good health and well-being for everyone *(12, 40)*. Prosthetics and orthotics services play an important role in achieving this goal and also other SDGs: access to education

and jobs, escaping poverty and hunger, equal access to opportunities and services and participation in society on an equal basis. These services are thus a precondition for achieving those goals and rights for a section of the population.

Challenges

Some challenges in developing prosthetics and orthotics services in the four core areas are listed below.

Area	Challenge
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, as these services are 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. 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, some of which offer products of poor quality, while rich populations are frequently served by private clinics. • Prosthetics and orthotics services are frequently perceived as an expense rather than an investment.

The degree to which these challenges manifest themselves depends on the country, but they are present in all parts of the world. It is likely that up to 90% of the people who need prosthetics and orthotics services do not have access to them, as they are neither affordable nor available. For many poor and marginalized populations, the reality is that these services just do not exist.

The aim of this document is to improve this situation, with the goal that everyone in need, everywhere, has access to prosthetics and orthotics services; "no one should be left behind", as stated in the SDGs *(12)*. The standards in the document can help Member States to ensure that people have access to high-quality services irrespective of their socioeconomic condition, thus fulfilling the ultimate goals of the CRPD and the SDGs. The document urges gender-sensitive prosthetics and orthotics services, including more women in the workforce.

Box 4. Paulina's story, Mexico

When Paulina was 17 years old, her leg was amputated because of a tumour. Paulina feared that she would never be the same – that it would be impossible for her to lead an independent life. She also thought that she would not be able to find a partner, to have children or to have a career that would allow her to sustain herself. Paulina was using a prosthesis, but it was not without problems. Luckily, she found a passionate, creative, professional prosthetist who made a new socket. This represented a complete change and a real opportunity for her. Although she was still using the same knee and foot that she had used for two years, Paulina felt really comfortable and in control of her prosthesis for the first time. Her life changed almost immediately. She decided to study journalism, which led her to find a job on a newspaper, where she met the man of her dreams, with whom she has shared her life ever since and who is the father of her two children. Since she has had the new prosthesis, Paulina has tried athletics and taken up yoga. She dances, travels and walks and has a full, independent, enjoyable life.

She says, "My life is certainly different, but now I know there's nothing to be afraid about. My prosthesis allows me to have the kind of life that I want."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Area 1. Policy

1.1 Leadership and governance

Introduction

Leadership and governance of the development and management of prosthetics and orthotics services are frequently lacking in Member States. These services require governance, combined with the knowledge, skills and resources of a range of organizations, institutions, agencies and individuals. A network of organizations and people has a combined power that is greater than the sum of the parts.

1.1.1 Stakeholders and coordination

Rationale

Where the involvement of stakeholders is weak, any service risks stagnation. This is also true for the provision of prosthetics and orthotics services. The contributions of a wide range of stakeholders with specific and complementary skills and resources, including users, caregivers and user groups, ensures that well-functioning, effective services are established, maintained and continuously developed. As outlined in the CRPD, Member States have the responsibility to promote the availability and use of high-quality assistive products and technologies, including prostheses and orthoses, at an affordable cost to users *(41)*. As governments have the power to set the agenda and to make policy decisions, they can bring together all relevant stakeholders in planning, developing and monitoring prosthetics and orthotics services, with the shared goal of ensuring countrywide access. A national prosthetics and orthotics committee or a similar entity established within the structure for coordination of health services, including rehabilitation, provides a foundation for strengthening collaboration and coordination and developing service provision.

NO.	STANDARD
1	Governments should assume a leading role in the development and coordination of national prosthetics and orthotics service provision.
2	Governments should involve all relevant stakeholders – including service users, caregivers and user groups – in policy development, planning, implementation, monitoring and evaluating prosthetics and orthotics services.
3	A national prosthetics and orthotics committee or similar entity, with a wide range of stakeholders, should be in place for the coordination and development of national prosthetics and orthotics service provision.

Related topic in the implementation manual:
1A Stakeholders and their roles

1.1.2 Guiding framework for prosthetics and orthotics service provision

Rationale

Most countries have no guiding framework for prosthetics and orthotics services; this holds back service development. A framework, consisting of legislation, policies, strategic plans, standards, rules and regulations, is necessary to establish and maintain appropriate services. A policy on prosthetics and orthotics, preferably an integral part of broader policies for health, rehabilitation, disability and assistive technology, defines the overall aim for service development. More detail is given in a national strategic plan, jointly developed by all stakeholders. Establishing standards for each area of work and systems for licensing services and the accreditation of professionals contribute to making prosthetics and orthotics services more affordable, accessible, effective, efficient, safe and of higher quality. In the same way as for other health services, prosthetics and orthotics services should be regulated by the State.

NO.	STANDARD
4	There should be a national guiding framework for prosthetics and orthotics service provision.
5	Prosthetics and orthotics service provision should be regulated by the State.

Related topic in the implementation manual:
1B Guiding framework

1.1.3 Monitoring

Rationale

Although some countries have established plans for prosthetics and orthotics service provision, progress in implementation is rarely measured. Member States have a responsibility to ensure that service provision is appropriately monitored by national stakeholders, possibly by a national prosthetics and orthotics committee (or similar entity). Monitoring can ensure that services meet the goals set in national policies and strategic plans and that service providers abide by national regulations. Successful monitoring requires establishing appropriate procedures, using the right tools, defining measurable goals, benchmarks and performance indicators and collecting data systematically.

NO.	STANDARD
6	Prosthetics and orthotics service should be monitored nationally and regionally.

Related topics in the implementation manual:
1C Monitoring
1O Collection of data

1.1.4 International coordination and cooperation

Rationale

In the absence of capacity, resources and expertise, many countries find it difficult to establish and develop prosthetics and orthotics services. As outlined in Article 32 of the CRPD, international cooperation in the form of technology and knowledge transfer is essential, as it can speed up the development of services, particularly in low- and middle-income countries.

Governments and other stakeholders should ensure that they have up-to-date information about international developments in prosthetics and orthotics so that evidence-based best practice is applied in national service provision. Communication of local experience to the international prosthetics and orthotics community increases knowledge at global level. International bodies, such as WHO and ISPO, and higher education establishments can coordinate the exchange of research results and evidence-based practice.

NO.	STANDARD
7	Governments and national stakeholders should collaborate internationally and share experience, data and research on prosthetics and orthotics service provision.

1.1.5 International support

Rationale

In many countries, support by international organizations and nongovernmental organizations (NGOs) is important in establishing and strengthening prosthetics and orthotics service provision and professional training *(42, 43)*.

International support is most effective when it complies with national health and welfare policies and strategic plans or, if these do not exist, contributes to their development. International organizations are most likely to produce long-term results and contribute effectively to building sustainable services when they work within and strengthen and further develop national systems *(27)*. This requires expertise not only in technical issues in service provision but also in policy-making, systems development, sector planning and financing.

NO.	STANDARD
8	International support, when provided, should contribute to the establishment and implementation of national prosthetics and orthotics policies and strategic plans and be aligned with the provision system of the national health and welfare service.

Related topics in the implementation manual:
1D International support
4J Service provision in disasters

1.2 Financing

Introduction

The aim of universal health coverage is to ensure that people can access all health services, including prosthetics and orthotics services, without suffering financial hardship. Sustainable funding must be available for the provision of services to all in need *(44)*. Planning and budgeting should be based on a comprehensive analysis of costs and benefits.

1.2.1 Economic analysis of prosthetics and orthotics service provision

Rationale

The overall costs and economic benefits of prosthetics and orthotics service provision are rarely understood by those who set policies. Information on costs is necessary for assessing the full financial implications of providing a population with prostheses and orthoses. At national level, costs should be analysed for five distinct areas: service establishment, training of human resources, provision of services, expenses of service users and system monitoring. These areas cover the full cost of prosthetics and orthotics treatment, indicating the financial resources necessary to assist the population. At service level, data on the full cost of each of the main types of treatment and product makes it possible to set the correct prices and prepare a budget.

Investment in prosthetics and orthotics services generates financial returns to individuals, their families, caregivers and wider society as people become healthier and need less support; many are able to return to work *(45)*. Both individuals and society accrue benefits, and the financial return on investing in this sector is an important argument for service provision. The financial implications are best understood by comparing the economic benefits with the investment. Comprehensive data on costs and benefits allow relevant ministries (such as those for health, social welfare and finance) to make informed decisions for planning and budgeting prosthetics and orthotics services and to recognize that the cost burden on one ministry may be offset by savings in another.

NO.	STANDARD
9	The cost of providing prosthetics and orthotics services should be assessed periodically.
10	The direct and indirect economic benefits of prosthetics and orthotics services should be analysed at individual, family, community, society, health sector and national levels.

Related topics in the implementation manual:
1E Costs
1F Economic benefits
1G Ensuring cost–effectiveness
1H Benefits of early detection and treatment of impairments
1I Prevention of avoidable impairments

1.2.2 Funding prosthetics and orthotics services

Rationale

The funding of prosthetics and orthotics services is a challenge for most Member States. These services are nevertheless part of health care and rehabilitation and must be taken into account or be included in health services when countries move towards universal health coverage *(22)*. As for other health services *(46)*, people who need prosthetics and orthotics services should have access to them without suffering financial hardship.

The inclusion of prosthetics and orthotics services in universal health coverage requires appropriate financing models and government commitment. The allocation of resources to disability services has been identified as important for strengthening and improving access to rehabilitation services and protecting people from burdensome expense *(3, 47)*. Access is improved by including these services in national public health and social insurance systems *(48)*. As appropriate in the local context, complementary sources of (often mixed) funding, such as private health insurance and medical savings accounts, trust funds, credit unions, private institutions, multinational companies, corporate social responsibility initiatives, cross-subsidies, community health financing and private donations, can help to make the services affordable.

NO.	STANDARD
11	Prosthetics and orthotics services should be an integral part of universal health coverage.
12	Prosthetics and orthotics services should be included in national health and social insurance systems, like other health interventions.

Related topics in the implementation manual:
1J Universal health coverage
1K Financing
1L Considerations in applying service fees
1M Facilitating access of users

1.3 Information

Introduction

Governments and other stakeholders must have access to reliable data on the total and unmet needs for prosthetics and orthotics in order to plan and monitor the sector adequately.

Rationale

Accurate data on the national need for prosthetics and orthotics are rarely available; however, information on how many people require services, of what type and where they live is indispensable for planning and developing countrywide services for all. In collecting such data, it is important to recall that most users require their prosthesis or orthosis for life, with regular replacements.

Data are also required for monitoring, to understand how many people have access to the services and who they are. They allow verification of the quality, effectiveness and efficiency of services and ensure that improvements can be made *(49)*. For service units, data are best collected during day-to-day work from existing user management systems. Much of this information is useful in monitoring prosthetics and orthotics service provision to evaluate whether they are developing according to national plans.

Establishment of a national database on provision and outcomes will facilitate data collection, monitoring, analysis and exchange and comparisons of data among service providers.

NO.	STANDARD
13	Data on prosthetics and orthotics service provision should be collected periodically, analysed at service level and shared at national level.
14	A national prosthetics and orthotics database should be established to identify total need, types of need and unmet need.

Related topics in the implementation manual:
1N Assessing the need
1O Collection of data
1P Data on impact

1.4 Promotion of prosthetics and orthotics services

Introduction

The general population, and even health workers and intended service users, are often unaware of the purpose and benefits of prosthetics and orthotics services. As a result, many people who need the services are excluded and in poor health. Awareness-raising and promotion of these services is therefore as important as for any health programme.

Rationale

People who need prosthetics and orthotics services often do not know about them. Governments are obliged to provide accessible information about these services to people with disabilities and about mobility aids, devices and assistive technologies, including prostheses and orthoses *(8)*. All stakeholders, including users and service providers, should raise awareness about policy and referral. When the need, role and benefits of prosthetics and orthotics services are explained, they become more visible and more accessible for new user groups *(41)*. The impact of awareness-raising campaigns is enhanced by targeting various audiences and use of rights-based, social and economic arguments.

NO.	STANDARD
15	Strategies for raising awareness about prosthetics and orthotics services should be established, including rights-based, social and economic arguments.

Related topics in the implementation manual:
1Q Awareness-raising
1R Strengthening the image

Box 5. Husam's story, Syrian Arab Republic

In 2013, when Husam was 26 years old, his life took a sharp turn. He was walking alone on the outskirts of his village in the suburbs of Damascus in a supposedly safe area on a soundless street, but an unexpected shell broke that silence and, in an instant, Husam, a university graduate, became a bilateral trans-tibial amputee. Without access to good surgery or a prosthetics service, Husam had to endure painful prostheses made from fibreglass, used in mending boats, by a warehouse keeper. As he could not walk on them, he gave them up after one week. After operations on his amputation stumps for multiple problems, he eventually received his first "real" prostheses.

Currently, as director of a rehabilitation centre for his injured fellow countrymen, he has one dream:

"To bring happiness to as many injured people as possible."


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Area 2. Products

2.1 Types

Introduction

There are various types of prostheses and orthoses, with different components, materials and working methods. Services may provide combinations of basic, intermediate and advanced products that are prefabricated or custom-made, locally available or imported. The complexity of services ranges from the provision of an off-the-shelf product fitted in one short session to custom-made products that may take days or weeks to make. The products and methods should be appropriate to the setting in which they are fabricated, fitted, used and funded to ensure that prosthetics and orthotics services are available to all.

Rationale

Service users do not use prostheses or orthoses if they are inappropriate. Products are appropriate when they provide proper fit and alignment, suit the needs of the individual and can be sustained by the country at the most economical price *(1, 50, 51)*. Nationally agreed criteria help to assess the appropriateness of the available options and ensure that service providers offer the best mix and range of products for the local context. The mix may vary among and within countries and over time. Regular exploration of the market and evaluation of alternative products, components, materials and consumables ensure that the most appropriate working methods and products are in use.

Establishment of a national list of priority prosthetic and orthotic products (as part of a national list of priority assistive products) helps governments to fulfil their commitment to ensure access to high-quality assistive products at an affordable cost, as mandated by the CRPD *(8)*. Such a list and appropriate financing will improve access to assistive products, including prostheses and orthoses *(2)*.

A national classification of prostheses and orthoses based on the classification of the International Organization for Standardization (ISO) *(6, 52-54)* will harmonize prescription practice and facilitate exchange of information on prosthetics and orthotics nationally and internationally.

NO.	STANDARD
16	An appropriate range of prosthetic and orthotic products should be available in countries to suit local needs and realities.
17	A national list of priority prosthetic and orthotic products should be drawn up, respected and updated regularly.
18	International standards should be used for national classification of prosthetic and orthotic products.

Related topics in the implementation manual:
2A Appropriate technology
2B Overview of product features
2C Prefabricated and custom-made products
2D Priority assistive products
2E ISO categorization
4P, Box 26. ISO standard terminology for prosthetics and orthotics

2.2 Supply of materials

Introduction

A range of components, materials and consumables are required to make a prosthesis or orthosis. Some can be purchased locally and some will have to be imported.

Rationale

In order to fabricate high-quality prostheses and orthoses most efficiently, prosthetics and orthotics service units require high-quality components, materials, consumables, tools, machines and other equipment, some of which are often imported. In many countries, the cost of the final prosthesis or orthosis is greatly increased by high import duties and taxes on imported supplies. Exemption from import duties and customs fees of items that are used exclusively to fabricate prostheses and orthoses but are not available in the country contributes to lowering prices and to fabrication of high-quality products at an affordable price.

Reuse of prosthetic and orthotic components must be monitored properly to prevent use of low-quality, overused or defective items, which could result in accidents and injuries. Regulation by a designated authority or group of experts and refurbishment of items under controlled conditions protect user safety.

NO.	STANDARD
19	Components, materials, consumables, tools, machines and other equipment used exclusively for fabrication of prosthetic and orthotic products that are not available in a country should be exempt from import duty and customs fees.
20	Reuse of prosthetic and orthotic components should be regulated by a designated authority or group of experts with no conflict of interests and involve proper quality control and documentation.

Related topics in the implementation manual:
2F Supply of components and materials
4M Equipment

2.3 Technical standards

Introduction

Member States are responsible for ensuring that quality-assured components and materials are used in the fabrication of prostheses and orthoses through national regulation and product testing and by applying national and international standards.

Rationale

Many countries do not have national prosthetics or orthotics product standards. State regulation is central to increasing access to safe, effective, high-quality prostheses and orthoses *(55)*. As these are health products, a regulatory system for products and for the components and materials used in prostheses and orthoses is best established as an integral part of national health care regulation *(7, 56)*.

Structural testing of prosthetic and orthotic components and materials demonstrates their compliance with ISO or equivalent requirements and ensures that they are strong, durable and safe *(57)*. In addition to structural testing, clinical field tests can be used to verify that prosthetic and orthotic products are fit for purpose. The use of national or internationally recognized scientific testing methods ensures the reliability, validity and comparability of results globally.

NO.	STANDARD
21	National regulation of prosthetic and orthotic products, components and materials should be an integral part of the national health care regulatory system.
22	Prosthetic and orthotic products should be tested structurally for compliance with ISO or equivalent standards before being sold on the market.

Related topics in the implementation manual:
2G Regulation of technical issues
2H Structural and clinical testing

2.4 Research and development

Introduction

Technical and clinical research and innovation improve prosthetics and orthotics. More evidence on the cost–effectiveness and quality of treatments and products will ensure that appropriate prosthetics and orthotics services become accessible to more people who need them.

Rationale

Evidence of the appropriateness of technologies and methods and of the effectiveness and cost–effectiveness of treatments is generally lacking in the prosthetics and orthotics sector, and more national and international research will advance both practice and services. A major limitation is inadequate training of prosthetists and orthotists to conduct research. Organizations and higher education establishments in countries should encourage and conduct research and train these professionals to conduct studies and exchange, disseminate and apply the findings.

In order to increase the number of people in less-resourced settings who receive assistance, new, affordable products and methods are needed, with mass production of cost–effective, quality controlled, context-appropriate components. Although research and development has led to important technical advances *(58)*, the availability of products has not materially increased for most people in low- and middle-income countries. While governments are responsible for making new products available at an affordable cost *(8)*, this can be achieved only with the involvement of a range of national and international stakeholders, including the private prosthetics, orthotics and health care industry, and with targeted international funding.

NO.	STANDARD
23	Clinical and technical research should be conducted in prosthetics and orthotics, and the results should be shared nationally and globally.
24	Affordable prosthetic and orthotic products that are cost–effective, of good quality and context-appropriate should be developed and made widely available.

Related topics in the implementation manual:
2I Technical and clinical research
2J Development of affordable products

Box 6. Camara's story, Mali

Camara was born in a farming family 90 km from Mali's capital, Bamako. His left arm was amputated when he was nine after a poorly treated fracture sustained after falling from a tree. He studied hard and graduated with a diploma in accounting in 2006 but was disappointed not to be selected for the Malian civil service.

He received an arm prosthesis five years ago, which gave him the courage to embark on a new venture – mending car tyres and motorcycles in Bamako; he also sells motorcycle parts.

Camara says "This activity allows me to satisfy the needs of my little family". He explains the advantages of the prosthesis: "I do all my activities with the prosthesis. I am no longer different from others, I do the bonding of tyres, play football, ride a motorcycle and even, when I go back to visit my parents in the village, sometimes plough the field with the oxen."

Camara is generally satisfied with his prosthesis, although he finds that the hand is a problem, as it frequently needs repair or replacement.

Area 3. Personnel

3.1 Personnel who provide prosthetics and orthotics services

Introduction

Like other health care personnel, those in prosthetics and orthotics services comprise professionals, associates and assistants, with two broad job profiles: clinicians (prosthetists and/or orthotists and their associates) and nonclinicians (technicians and support staff). In collaboration with a team of health care, rehabilitation and administrative personnel, they provide prosthetics and orthotics treatment for people with diverse physical impairments or functional limitations. Therapists, nurses, physicians, pedorthotists, pedorthists, podiatrists and other health care professionals may independently provide a limited range of orthoses or mobility devices, provided they have the right training and skills.

Rationale

There are significant shortages of prosthetics and orthotics personnel in all parts of the world. The provision of high-quality prostheses and orthoses depends on the availability of competent, adequately trained clinicians and nonclinicians and other health care personnel. While many people with a physical impairment or functional limitation can be treated by prosthetics and orthotics personnel alone, those with severe or complex health problems or deformities often require interventions by a range of other health and rehabilitation professionals. A multidisciplinary team with an appropriate mix of knowledge and skills can provide timely, effective treatment *(59-61)*. Multidisciplinary teamwork is important in rehabilitation *(10, 62)*, including in prosthetics and orthotics *(63-65)*.

NO.	STANDARD
25	Prosthetics and orthotics services should be provided by competent, adequately trained professionals.
26	Complicated prosthetics and orthotics treatment and care of complex cases should be provided by a multidisciplinary team of professionals with complementary skills.

Related topics in the implementation manual:
3A Service unit personnel
3B Other professionals on the team
3C Multidisciplinary rehabilitation teams

3.2 Training in prosthetics and orthotics

Introduction

The capacity of prosthetics and orthotics personnel is built by structured training and continuing professional development (CPD). Other health, allied health and social care personnel also require knowledge of prosthetics and orthotics, as required by their position in health and social care systems and their degree of involvement in prosthetics and orthotics work.

3.2.1 Core personnel

Rationale

Despite the expansion and development of prosthetics and orthotics training programmes during the past three decades, the number of personnel required, both clinicians and nonclinicians, continues to largely exceed the supply. More transformative training and education are required to address the need *(66)*. Without an increase in the number of personnel, access to prosthetics and orthotics services will remain inadequate, uncertain or even at crisis point.

Training according to international and national standards, such as those of ISPO, equips students with the minimum competence required for safe, effective practice in each professional category, although more work is needed to determine the exact influence of training and education on the quality of prosthetic and orthotic services *(23, 67–79)*. ISPO suggests that prosthetists and orthotists be trained at the same level as allied health care professionals, associate prosthetists and orthotists at the level below that of allied professionals, and technicians at the same level as health care assistants *(80)*. Training at different levels ensures that service needs are met in all settings at all levels of resources, including decentralized services. Planning training as a continuum allows professionals to move from one level to the next.

NO.	STANDARD
27	Training in prosthetics and orthotics should be aligned with national and international educational standards.
28	Training in prosthetics and orthotics should be available at various levels to fully meet national needs.

Related topic in the implementation manual:
3D Training of prosthetics and orthotics personnel

3.2.2 Other personnel

Rationale

All health care and allied health and social care personnel should have a basic understanding of prosthetics and orthotics, so that they can identify and refer people for treatment and coordinate care *(81–83)*. Professionals who work in or with prosthetics and orthotics services, such as members of a multidisciplinary team, should have a more profound understanding of

the work *(84, 85)*. Practice should be based on best available evidence and follow international recommendations *(86-89)*. When prosthetics and orthotics services are mainstreamed into health care systems (see section 4.2.1), training should also be provided for primary health care personnel, who are often the best source of referrals and follow-up.

NO.	STANDARD
29	Health care professionals, especially rehabilitation professionals, who provide treatment relevant to prosthetics and orthotics services should have adequate knowledge about prosthetics and orthotics.

Related topic in the implementation manual:
3E Training other professionals in prosthetics and orthotics

3.2.3 Continuing professional development

Rationale

Opportunities for CPD are severely lacking, especially in poorer settings *(73-78, 90-92)*. CPD provides prosthetics and orthotics personnel with a variety of learning opportunities and experiences to maintain and develop their practice and ensure that they can continue to work effectively and safely in an evolving field. CPD is fundamental to securing and improving the quality of services provided by professionals at all levels. It also allows experienced personnel who have received little formal training to update their knowledge and practical skills, maximizing their motivation and capacity. Prosthetics and orthotics personnel have a duty to find and engage with their own CPD. To this end, the workplace should offer a stimulating learning environment in which personnel are encouraged to reflect on their everyday practice.

NO.	STANDARD
30	Continuing professional development should be compulsory in prosthetics and orthotics professional practice.

Related topics in the implementation manual:
3F Continuing professional development
3G Role development

3.3 Planning the prosthetics and orthotics workforce

Introduction

Prosthetics and orthotics services must be planned to ensure that the right numbers of personnel with the appropriate competence are present at all levels of health service delivery: primary, secondary and tertiary (see section 4.2.1).

Rationale

In many countries, the workforce for prosthetics and orthotics services is not planned, so that the right personnel may not be in the right locations. Workforce planning involves determining the demand for personnel, comparing it with the existing supply and assessing training needs. Evaluating the availability of all the disciplines involved in prosthetics and orthotics service provision can ensure that the workforce is well balanced throughout the service delivery system.

Workforce planning is central to planning effective prosthetics and orthotics services *(93–95)* and can provide essential information for national health and welfare planning. Involvement of relevant national stakeholders, such as training institutions, user groups, service providers, employers, commissioners of services and funding agencies, helps to ensure that the workforce is adapted to the local context and can be made available.

To safeguard the quality of prosthetics and orthotics services, at least one experienced prosthetist and orthotist should be available at each service delivery unit. This person will be responsible for the quality of the services delivered, by supervising and mentoring associate professionals, technicians and support staff *(96)*.

Strategies are needed to retain prosthetics and orthotics professionals so that they are motivated to engage fully in service delivery and remain in the profession, even in rural and remote settings *(97)*. This will maintain the quality and efficiency of services and ensure that investment in training has its intended long-term impact.

NO.	STANDARD
31	Workforce planning should take into account all the disciplines required in prosthetics and orthotics services at all levels.
32	Prosthetics and orthotics service units should have at least one prosthetist and orthotist to supervise and guide clinical and technical work.
33	A strategy to retain prosthetics and orthotics personnel should be in place.

Related topics in the implementation manual:
3H Workforce planning
3I Retention of personnel

3.4 Professional regulation and recognition

Introduction

Regulations are required for health professionals, including prosthetists and orthotists, in order to enforce accountability of conduct and practice and reduce the risk of users for harm. Professional recognition gives adequate importance to prosthetics and orthotics personnel and the services they provide and is linked to regulation. Recognition is a precondition for regulation, and regulation further increases recognition.

Rationale

Many countries do not have professional regulation or recognition of prosthetists and orthotists, placing service users at risk for malpractice and poor-quality services. The introduction of professional regulations protects service users from these risks. The regulations should define the minimum levels of education and experience required for these professionals to practise and the permitted scope of work. State regulation of prosthetics and orthotics clinicians harmonizes clinical practice.

All personnel in prosthetics and orthotics services throughout the health system should be accountable for their actions. A part of this accountability is achieved by prosthetists and orthotists assuming responsibility for the services provided by associate and nonclinical personnel under their supervision.

Recognition of prosthetics and orthotics clinicians as health professionals with distinct professional titles and profiles firmly establishes these services in the national health service and increases the motivation, retention and professional development of personnel, which in turn enhances service provision. Recognition implies that these clinicians have a clear career structure and that their employment conditions are aligned with those of other health professionals. The classification of prosthetists and orthotists should correspond to that of physiotherapists and occupational therapists, as they have similar levels of responsibility. Correct classification of prosthetists and orthotists is an incentive, as it offers increased opportunities for promotion.

NO.	STANDARD
34	Prosthetics and orthotics clinicians should be regulated by the State within regulations for health professionals.
35	Prosthetists and orthotists should assume responsibility for services provided by associate and nonclinical personnel under their supervision.
36	Prosthetics and orthotics personnel should have a clear career structure and employment conditions that are aligned with those of other health care professionals, associates and technical personnel.

Related topics in the implementation manual:
3J Professional regulation
3K Professional recognition
3L Professional associations and societies

Box 7. Bishnu's story, Nepal

Because of lack of proper, timely treatment of a right leg fracture in Bishnu's early childhood, a severe bone infection developed that led to shortening and weakening of her leg.

For years, Bishnu struggled to access a well-fitting leg orthosis and shoe raise. Despite pain, she was able to continue her education. An orthosis changed her life completely, as she became more mobile and developed a wider social network. She took opportunities for higher education and employment and today has a PhD in Gender and Development Studies from the Asian Institute of Technology in Bangkok, Thailand. She currently works as a freelance expert in gender and disability nationally and internationally. She is empowered socially and economically and has become a role model for many. She travels extensively for both study and work.

Bishnu has been using the most comfortable orthosis in her life for four years now after finding a skilled, committed orthotist who listened to her.


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Bishnu stresses, "Proper assessment of the user and attention to both major and minor things in designing the orthosis will provide solutions for complicated cases like mine. I consider my orthosis and shoe as part of my body and take good care of them."

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Area 4. Provision of services

4.1 User-centred service delivery

Introduction

Prosthetics and orthotics services should embody the principles of people-centred health services, "an approach to care that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems" *(7)*.

User-centred prosthetics and orthotics services[1] go a step further to ensure that every user with a physical impairment or functional limitation can make informed decisions about her or his care, services and service providers. 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 *(98, 99)*.

Rationale

Every prosthetics and orthotics service user has the right to be treated with respect and dignity. Users should receive effective, efficient services in a user-friendly, safe environment, in which their privacy and confidentiality are guaranteed. Service providers have the duty to share information about the results of assessments with users and caregivers and to explain treatment options, including products, technologies and materials, so that users can make decisions about their care. A written "user policy", prepared by users, caregivers and service providers, protects user rights and reinforces the practice of user-centred services. The success of a user policy requires that all service personnel receive adequate training in its purpose and use.

Users and their families, caregivers and organizations have unique insight into users' needs and situations; they are therefore indispensable in sustaining high-quality prosthetics and orthotics services. Their involvement in policy development, planning, implementation, monitoring and evaluation of services is essential, formalized by their representation on prosthetics and orthotics committees (or similar) at national and service levels. To optimize the contributions of users, stakeholders should be responsible for building their capacity.

The choice of service providers and products by users will help in matching long-term provision with the preferences of the service user, thus improving user satisfaction. When

[1] Unlike general health services, which are for all people, prosthetics and orthotics services are for a defined group of users. On the basis of the principles of people-centred health services, this document uses the term "user-centred prosthetics and orthotics services".

funding reflects users' choices, healthy competition is stimulated among service providers to improve the quality of their services and make delivery more efficient and cost-effective.

NO.	STANDARD
37	A documented policy to safeguard the rights of users of prosthetics and orthotics services should be in place and in effect, outlining the features of user-centred services.
38	Service users and their representatives should be involved in policy-making, planning, implementing, monitoring and evaluating prosthetics and orthotics services, take part in decision-making at all levels and be represented on relevant committees.
39	Service users should be given the opportunity to choose their service provider and technology, including components and materials, according to their need, among the options available in the country and the limits set for financing or reimbursement.

Related topics in the implementation manual:
4A User policy
4B The user: a central resource in planning and provision of services
4C The right of users to choose their service provider and technology

4.2 Systems for delivering services

Introduction

In order to reach all people in need, prosthetics and orthotics services are best planned and delivered through a system tailored to the needs, expectations and distribution of the population, with careful consideration of the resources available. Different services are needed at primary, secondary and tertiary levels, with standardized referral pathways. Mainstreaming prosthetics and orthotics services into national health care programmes contributes to attaining the goal of universal health coverage. Special considerations are required when delivering services in disaster contexts.

4.2.1 Inclusive service delivery

Rationale

Access to prosthetics and orthotics services is inequitable in many countries, whereas the principle of equal access to health services *(11)* is also applicable to these services. This implies that services are available for every person's needs and choices, without discrimination and regardless of the person's health, gender, age or socioeconomic circumstances.

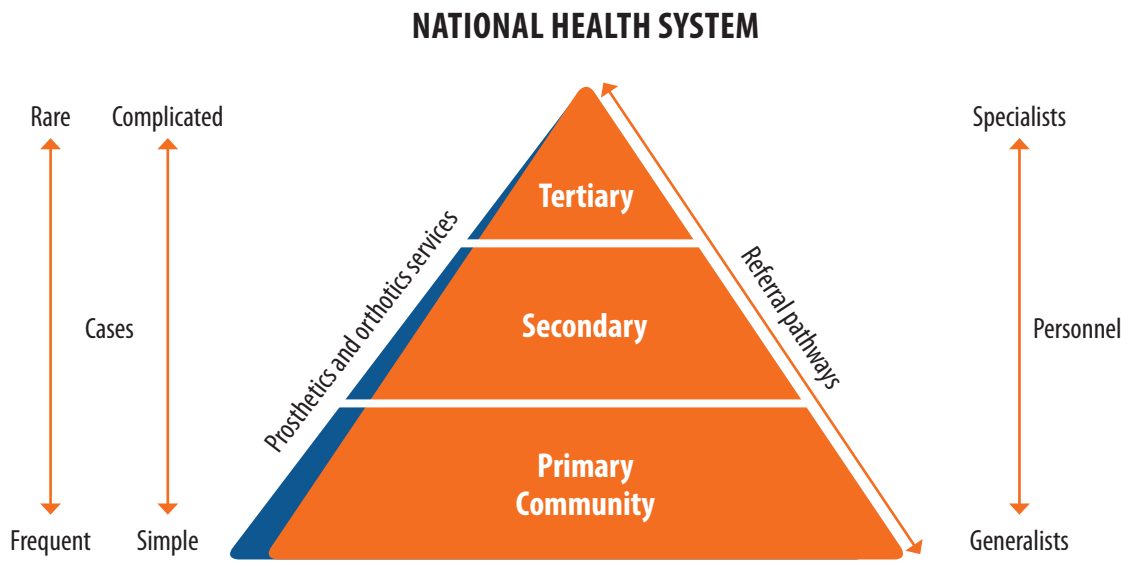
Prosthetics and orthotics services provide treatment for a range of health conditions *(100)*. They are related to other health services, such as medical, surgical, rehabilitation and therapy, with which they frequently interact and may share resources and outcomes. The inclusion of prosthetics and orthotics services in the health sector contributes to inclusive health services for all, including for people with disabilities and people with chronic health conditions.

Strong links and coordination among prosthetics and orthotics, health, rehabilitation and other sectors are essential for the provision of prosthetics and orthotics services. Not only the ministry of health but also the ministries of social welfare, labour, defence, education and

finance, local government, NGOs and the private sector all make important contributions to prosthetics and orthotics services. Intersectoral coordination maximizes the reach and outcome of the services, ensures a smooth continuum of care and enhances overall health and rehabilitation outcomes, such as a return to work, education and community participation.

Application of a three-tier system with differentiated services at primary, secondary and tertiary levels of the health care system is likely to improve access to prosthetics and orthotics services *(26)* (Fig. 6). By offering a realistic range of treatments at each service level, the range of services will be as wide as possible and can be provided close to people's communities, including in rural areas *(101)*. In order to respond to the different needs of users, there should be established links and standardized referral pathways among levels of service. Thus, common, simple cases can be treated at primary level, while rare and complicated cases can be referred to secondary and tertiary levels, where the personnel are more specialized.

Fig. 6. Integration of prosthetics and orthotics services into the health sector



When prosthetics and orthotics services are included in national health care programmes, users can access important resources at the primary level. Inclusion of a limited range of prosthetics and orthotics services in primary health care (as decided at tertiary and secondary levels) extends the geographical reach of these services, so that more people can be assisted *(20, 101)*. This approach is of mutual benefit for both prosthetics and orthotics services and the health care system. Many treatments require a joint approach to be successful, including early detection of impairments followed by early intervention. A health care programme that includes prosthetics and orthotics can make this possible. Integration of these services into national health programmes requires training of personnel, particularly in primary health care.

Service provision in remote and rural areas is strengthened by decentralizing services through satellite and mobile units or linkage with community programmes, including community-based rehabilitation.

The provision of readily accessible maintenance and repair services ensures optimal functioning and comfort of products, maximizes their lifespan and thereby reduces the need for frequent renewals. This increases the cost-effectiveness of services and ensures that more people are assisted.

NO.	STANDARD
40	Prosthetics and orthotics services should be accessible to all the people who need them: girls, boys, women, men and older adults.
41	Prosthetics and orthotics services should be part of the health sector or be closely linked to it.
42	Prosthetics and orthotics services should be delivered in a three-tier system, at primary, secondary and tertiary levels, with established links and two-way pathways for referral and follow-up.
43	Maintenance and repair services should be an integral part of a prosthetics and orthotics service delivery system.

Related topics in the implementation manual:
4D Accessible services
4E Types of service provider
4F Inclusion of prosthetics and orthotics services in the health sector
4G Service delivery systems
4H Decentralization of services
4I Maintenance and repair services
1J Universal health coverage

4.2.2 Inclusive service delivery in disaster contexts

Rationale

Prosthetics and orthotics services are required urgently for victims of natural or man-made disasters, such as earthquakes and armed conflict. In order to respond to such needs promptly, services are best provided by using, strengthening and, if necessary, rebuilding the local service system. The application of technologies and working methods that are compatible with those planned for the long term ensures that disaster victims can receive continuous support from well-functioning services once the disaster situation is over. Coordination of stakeholders ensures that the available resources are used effectively. By integrating prosthetics and orthotics services into the health sector response and by encouraging governments to take a leading role in coordination, prosthetics and orthotics services can be firmly established as an integral part of the long-term health care agenda.

NO.	STANDARD
44	The provision of prostheses and orthoses in disaster conditions should be an integral part of the health sector response and be planned to ensure a seamless transition to long-term service provision.

Related topic in the implementation manual:
4J Service provision in disasters

4.3 Service units

Introduction

A prosthetics and orthotics unit provides a space for professionals and users to interact and for the design, manufacture, customization, fitting, delivery and maintenance of prostheses and orthoses. The unit should be properly planned, appropriately equipped and offer a safe environment for users and personnel so that all processes are performed effectively and efficiently.

4.3.1 Settings

Rationale

Prosthetics and orthotics service units that are isolated from mainstream health care and rehabilitation services tend to have difficulty in developing and remaining efficient. The establishment of service units in health facilities, including those for rehabilitation, strengthens contacts with health professionals, facilitates multidisciplinary work, improves referral, generally speeds up treatment and improves overall outcomes.

Service units for the provision of a broader range of assistive devices (from prostheses and orthoses to other mobility devices, including wheelchairs and crutches, and other assistive products, such as devices for vision and hearing) may be a cost-effective way of providing comprehensive services to large user groups. This may be particularly important for older populations, who often require several types of assistive product.

NO.	STANDARD
45	Prosthetics and orthotics service units should be established within or closely linked to health and rehabilitation service facilities, such as district and referral hospitals.
46	The possibility of integrating prosthetics and orthotics service units into broader services for assistive products should be considered and explored.

Related topic in the implementation manual:
4K Exclusive and inclusive service units

4.3.2 Infrastructure

Rationale

By carefully designing prosthetics and orthotics units and adapting the layout and size to the intended workload and the types of services to be provided, individual needs can be met in a cost-effective, professional manner, and the unit can effectively contribute to meeting needs in the area *(102)*.

An accessible, barrier-free environment that provides privacy for every individual during service is essential. Ensuring that girls, boys, women and men can be treated separately makes services accessible to all, irrespective of gender or age.

NO.	STANDARD
47	At all service levels, prosthetics and orthotics units should be designed to ensure effective, efficient, high-quality service provision in a user-friendly, barrier-free, safe clinical environment.

Related topic in the implementation manual:
4L The service unit

4.3.3 Equipment

Rationale

Service units must be properly equipped. The choice of tools, machines and other equipment on the basis of price, quality, reliability and availability ensures the provision of long-term, cost-effective services of high quality. Regular maintenance of tools, machines and other equipment guarantees their proper functioning, prolongs their lifespan and helps to assure the safety of service providers and users. Every machine has a life; a plan for machine replacement is necessary.

NO.	STANDARD
48	Prosthetics and orthotics service providers should define and adhere to a plan for equipment maintenance and replacement.

Related topic in the implementation manual:
4M Equipment

4.3.4 Safety

Rationale

A prosthetics and orthotics service unit poses health and safety risks for both providers and users. These risks can be minimized by adherence to occupational health and safety regulations, training of personnel in safety and the use of tools and machines and provision and use of equipment for both personal safety (such as goggles, masks, work gloves and ear protection) and extraction of fumes and dust from work areas.

Systematic monitoring of safety and reporting, documentation and prevention of adverse incidents help to understand and minimize potential risks.

NO.	STANDARD
49	The safety of service providers and users should be ensured by the establishment of documented health and safety regulations.

Related topic in the implementation manual:
4N Working environment and safety

4.4 Service unit processes

Introduction

Appropriate processes for service delivery and service unit management ensure that all work is carried out systematically, effectively, efficiently and safely.

4.4.1 The service delivery process

Rationale

Inadequate clarity about the details of prosthetics and orthotics service provision – from referral throughout the delivery process – can lead to misunderstandings and inefficiency.

Referral is strengthened by informing and training partners – especially primary health care personnel, community health workers, community rehabilitation personnel, social workers and user groups – in identifying people who need prosthetics and orthotics services and referring them to the service unit.

After identification and referral, the delivery of prosthetics and orthotics services consists of assessment, fabrication and fitting, user training and product delivery and follow-up (Fig. 7).

Fig. 7. Steps in service delivery

The establishment of documented procedures and protocols for these four steps helps to ensure that services are consistent, effective and efficient in all phases of delivery. Their adequacy is further reinforced by application of minimum quality requirements based on the best available evidence and national and international standards.

Assessment: Every user of prosthetics and orthotics services should be assessed individually by a professional with appropriate knowledge and skills or, when possible and required, by a multidisciplinary team. The assessment should be holistic, taking into account the lifestyle, living environment and physical condition of the user. Active involvement of service users and caregivers in assessment, goal-setting and planning treatment ensures that the treatment will be the most appropriate for the user.

The provision of peer support in service delivery increases the motivation of users, may speed up treatment and contributes to improved outcomes.

Fabrication and fitting: Careful adherence to the manufacturer's or supplier's instructions on the use of components and materials can ensure that the full potential of products is used and hazards for users and personnel are minimized. When new products are used, prosthetics and orthotics professionals should be trained in their application to ensure seamless introduction, minimize technical problems and protect users.

User training: Training, including physiotherapy and occupational therapy, is critical to the outcome of prosthetics and orthotics treatment and helps to maximize the benefits of products *(65, 84, 103)*. Users who have insufficient training may be at risk for injury. Active involvement of family members and caregivers in training is critical for users who depend on regular support in their daily activities.

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Product delivery and follow-up: Before delivery of a prosthesis or orthosis, all its features must be checked according to a protocol to ensure the best possible quality, appropriateness and function. Consistently giving users and caregivers the opportunity to raise concerns during fitting and before the product is finalized contributes to ensuring a satisfactory final result. Effective provision of services requires a positive partnership between the service user and the provider, with shared decision-making and commitment to respect treatment and follow-up plans.

Evaluation of the outcome of treatment at the time of product delivery and in follow-up sessions will allow verification that the prosthesis or orthosis has the intended effect and the treatment goals have been met. Follow-up is required at certain intervals to review outcomes and ensure that there are no problems with the fit, comfort, function or durability of the device. Follow-up improves outcomes and is an indispensable part of service delivery.

NO.	STANDARD
	Identification and referral
50	Prosthetics and orthotics service providers should identify and train partners in identifying and referring potential users.
	Service delivery
51	All steps in the delivery of prosthetics and orthotics services should be based on the best available evidence and should adhere to local, national and international standards and practice.
	Assessment
52	Service providers should involve service users and caregivers in assessment, setting goals and planning treatment.
53	Peer support and counselling should be available to service users as appropriate.
	Fabrication and fitting
54	Prosthetics and orthotics personnel should follow the instructions and guidelines of the component manufacturer and document any deviation from standard practice.
	User training
55	Service users should be given sufficient training to ensure safe, effective use of prostheses and orthoses. Family members and caregivers should be involved as appropriate.
	Product delivery and follow-up
56	Users or caregivers should make the final decision about the acceptability of the fit and function of the prosthesis or orthosis.
57	The outcome of prosthetics and orthotics treatment should be evaluated and documented.
58	Prosthetics and orthotics service users should be followed up regularly.

Related topics in the implementation manual:
40 User identification and referral
4P The service delivery process

4.4.2 Management

Rationale

In general, there is little planning, monitoring or evaluation of prosthetics and orthotics services, which limits effective responses to service needs and understanding of outcomes. Annual and long-term strategic plans give direction to the development of services. Appropriate monitoring and evaluation of plans allows verification of progress and any corrections and improvements required *(104)*.

Quality management systems are used by service providers to monitor the quality of services and products. Quality control, which includes clinical audits, permits identification of weaknesses and appropriate measures to redress them. Defining quality requirements and controlling quality at all service levels (primary, secondary and tertiary) and for all types of service (including decentralized services and those within health and community work) ensure that all people in need have access to high-quality services. Application of quality requirements based on the best evidence and national and international standards ensures that both products and services are of consistently high quality.

Feedback from service users and caregivers is important for measuring quality and improving service provision. Surveys of service users covering all aspects of their experience and service provision are an essential part of quality management *(105)*.

NO.	STANDARD
59	Annual and long-term strategic and operational plans should be in place, with performance indicators for continuous monitoring.
60	The required quality should be defined and adhered to at all levels and in all parts of the prosthetics and orthotics service delivery system.

Related topics in the implementation manual:
4Q Service unit management
4R Quality management
1O Collection of data
1P Data on impact

Box 8. Kirsti's story, Norway

When Kirsti was 16 years old, she broke her back in a car accident and became totally paralysed from the waist down. Using an orthosis has become a natural part of her "clothing" because it reduces the pain in her spine and improves her balance. It has allowed her to study pharmacy and to have active leisure time.

Kirsti has always done sports; a highlight was winning a gold medal for cross-country skiing at the Winter Olympics in 1994. Now, she skis in her spare time in winter and often goes biking or canoeing with her husband in the summer.

A normal day starts with Kirsti leaving for work as a clinical pharmacist, which is an exciting job that she thoroughly enjoys. Every day she gets the opportunity to help determine the optimal drug therapy for patients in prisons, hospitals and nursing homes. After work, she usually goes shopping and then goes home to make dinner with her family.

Kirsti says, "I live a completely normal life like everyone else in Norway. The only difference is that I use a wheelchair instead of walking."

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The way forward

Despite adoption of the CRPD in 2006, today, only 1 in 10 people in need have access to assistive products, including prostheses and orthoses, because of high costs, poor awareness and a general lack of services, trained personnel, policy and adequate financing. When the services are available, the quality of the prostheses or orthoses is not always acceptable, adding more challenges for people with physical impairments or functional limitations.

Prostheses and orthoses should be available to all who need them. Their provision positively affects the health and well-being of users and their families and has broader socioeconomic benefits. These devices help people to become more active and to live healthy, productive, independent, dignified lives and to participate in education, the labour market and social life.

The set of 60 global standards presented in this document will assist Member States in setting up, improving and transforming national prosthetics and orthotics services, thereby contributing to improving access to high-quality, affordable services globally. This is a decisive step towards strengthening universal health coverage and making sure that "no one is left behind".

Strategy for implementing the standards

Implementing the standards should involve various stakeholders, including:

- service users, families and caregivers;
- user groups and disabled people's organizations;
- national, regional and local governments;
- civil society organizations;
- prosthetics and orthotics service providers (both public and private);
- health service providers, including those providing rehabilitation;
- training and academic institutions;
- professional associations;
- manufacturers and suppliers of components, materials and consumables;
- international organizations and agencies; and
- funding agencies.

The following steps are suggested for setting up or improving a national prosthetics and orthotics service and implementing the standards. More detailed guidance is provided in Part 2 of this document.

- Develop a national prosthetics and orthotics policy and a 5–10-year specific, measurable, achievable, realistic and timely ("SMART") action plan.

- Set up a nationwide prosthetics and orthotics service, integrated within the health system, to attain universal health coverage, the SDGs and related articles of the CRPD (articles 4, 19, 20, 26 and 32).
- Encourage public–private partnerships and financing to ensure that everyone in need, everywhere, has access to high-quality prostheses and orthoses.
- Ensure health or welfare insurance coverage to reimburse the cost of prostheses and orthoses.
- Establish a workforce and deploy them at secondary and tertiary levels, as a minimum.
- Ensure the availability of high-quality products, components and materials, and waive import duty and taxes on items that are not available in the country.
- Involve prosthetics and orthotics users, their caregivers and organizations in planning, implementing, monitoring and evaluating the plan.
- Audit prosthetics and orthotics standards, and assess needs periodically.

While the WHO standards can serve as a global guide, Member States should adapt them to their contexts, giving priority to standards that must be in place to safeguard user rights, safety, quality and performance. In countries with limited resources, some of the priorities, particularly those that require technical assistance, technology transfer or capacity-building, could be covered by the international cooperation framework defined in Article 32 of the CRPD.

Requirements for data and evidence

This document is based on the best available evidence; however, data and evidence on prosthetics and orthotics are lacking. Research and studies are required to obtain better data and to identify good examples of these services, including governance, sector planning, monitoring and financing. The following thematic areas are suggested as major global priorities for prosthetics and orthotics research:

- effects, costs and economic impact of prosthetics and orthotics services;
- policies, systems, service provision models and best practices;
- high-quality, affordable products;
- human resources for the provision of prosthetics and orthotics services; and
- standards and methods for assessing need and unmet need for prosthetics and orthotics services.

The precise research questions will depend on national realities; however, certain questions are suggested for consideration:

Effects, costs and economic impact of prosthetics and orthotics services

- What is the impact of prosthetics and orthotics services on the quality of life of people with disability, especially in terms of inclusion and participation?
- What are the social and economic impacts (e.g. return on investment) of different prosthetics and orthotics interventions?
- Which tools and methods are appropriate for measuring and comparing the costs of prosthetics and orthotics services relative to outcomes?

Policies, systems, service delivery models and best practices

- What should the key components of a framework and method be for setting up a national prosthetics and orthotics service policy?
- What implementation strategies have been effective in extending prosthetics and orthotics services to primary and community levels?
- What are the effective financing mechanisms for sustainable prosthetics and orthotics services in different countries?

High-quality, affordable products

- What technology radically increases access to prosthetics and orthotics services?
- What is the most cost–effective way of making high-quality prostheses and orthoses available?
- What factors influence the lifespan of prostheses and orthoses?

Human resources for the provision of prosthetics and orthotics services

- What skills and competence do prosthetics and orthotics personnel require at the primary, secondary and tertiary levels of health services?
- What are the cost–effective opportunities for training prosthetics and orthotics personnel at different levels?
- What are the realistic solutions and opportunities for involving other health professionals in prosthetics and orthotics services by task-shifting?

Standards and methods for assessing need and unmet need for prosthetics and orthotics services

- How can accurate data about the needs and unmet needs for prosthetics and orthotics services be collected at national and global levels?
- What are the essential components of a prosthetics and orthotics needs assessment?
- What essential components should be considered in drawing up an annual plan and budget for prosthetics and orthotics service provision?

Member States are urged to work with national and international stakeholders to conduct research, increase exchange of relevant information and successful models and expand the evidence base on prosthetics and orthotics services. International stakeholders in particular could support national research activities by:

- establishing mechanisms for global collaboration and coordination;
- identifying and standardizing research questions in consultation with countries and user groups;
- identifying and developing appropriate tools, methods and standardized data sets for collecting, analysing, comparing and sharing data and research results at national and international levels;
- increasing investment in research and studies, particularly in poorer settings;
- involving a broad range of experts, such as health economists, sector development specialists and human rights experts;
- working with designated regional and national centres of excellence; and
- encouraging regional collaboration and multi-country studies or meta-analyses.

Box 9. Dareen's story, Lebanon

At the age of 15, Dareen was found to have osteogenic sarcoma, a very aggressive bone cancer, and her life changed in an instant. She underwent 7 months of intensive chemotherapy, but ultimately her leg was amputated above the knee and she received a prosthesis. This traumatic life event resulted in a bout of depression and an identity crisis. Dareen had to learn to believe in herself again, to accept and to love herself just as she was; learning that she did not have to fit certain "standards" mandated by society. Life was challenging, but Dareen decided to take it one step at a time while she was also coming to terms with moving around on her prosthesis and the pain and stress of fitting it. She was determined to fulfil her dreams. In 2006, Dareen married, relocated with her company to the United Arab Emirates and, in 2010, was selected as one of the 40 "most inspiring women" in the Gulf States. Soon after the birth of her daughter, Dareen fell in her kitchen and broke the hip on the side of her amputated leg. She could not walk for three months, and she "became a slave to fast food and sugar". The fall necessitated use of a more advanced prosthesis, but Dareen had to have the body to match it. After turning her life around and embracing health and wellness to lose 25 kg, she received the new prosthesis. She saw a need to help other amputees and so started a Facebook support page. In 2015, she participated in the Dubai Standard Charter marathon race, completing a 4-km "fun run", and is now passionate about building her physical strength and stamina.

Her mantra is: "In order to change the world, we first need to change ourselves."

References

1. Report of a consensus conference on appropriate prosthetic technology for developing countries. Phnom Penh, Cambodia. Copenhagen: International Society for Prosthetics and Orthotics, 1996.
2. Priority assistive products list. Geneva: World Health Organization; 2016 (http://www.who.int/phi/implementation/assistive_technology/global_survey-apl/en/, accessed 30 August 2016).
3. World report on disability. Geneva: World Health Organization and The World Bank; 2011 (http://www.who.int/disabilities/world_report/2011/en/, accessed 30 August 2016).
4. International classification of functioning, disability and health: ICF. Geneva: World Health Organization; 2008 (http://www.who.int/classifications/icf/en/, accessed 30 June 2016).
5. Statement on occupational therapy. Forrestfield, WA: World Federation of Occupational Therapy; 2010 (http://www.wfot.org/Portals/0/PDF/STATEMENT%20ON%20OCCUPATIONAL%20THERAPY%20300811.pdf, accessed 30 June 2016).
6. ISO 8549-1: Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15800, accessed 11 January 2017).
7. WHO global strategy on people-centred and integrated health services: interim report. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/155002/1/WHO_HIS_SDS_2015.6_eng.pdf?ua=1&ua=1, accessed 30 Decembr 2016).
8. United Nations Convention on the Rights of Persons with Disabilities. New York, NY: United Nations; 2006 (https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/convention-on-the-rights-of-persons-with-disabilities-2.html, accessed 30 August 2016).
9. Policy statement: Description of physical therapy. Forrestfield, WA: World Confederation for Physical Therapy; 2011 (http://www.wcpt.org/policy/ps-descriptionPT, accessed 30 June 2016).
10. Rehabilitation in health systems. Geneva: World Health Organization; 2017 (http://www.who.int/disabilities/rehabilitation_health_systems/en/, accessed 17 March 2017).
11. Health financing for universal health coverage. What is universal coverage? Geneva: World Health Organization; 2016 (http://www.who.int/health_financing/universal_coverage_definition/en/, accessed 30 December 2016).
12. Transforming our world: the 2030 agenda for sustainable development. New York, NY: United Nations; 2015 (https://sustainabledevelopment.un.org/post2015/transformingourworld, accessed 30 December 2015).
13. Assistive devices/technologies: what WHO is doing. Geneva: World Health Organization; 2016 (http://www.who.int/disabilities/technology/activities/en/, accessed 30 August 2016).
14. 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 30 August 2016).
15. Gutenbrunner C, Negrini S, Kiekens C, Zampolini M, Nugraha B. The Global Disability Action Plan 2014–2021 of the World Health Organisation (WHO): a major step towards better health for all people with disabilities. Chance and challenge for physical and rehabilitation medicine (PRM). Eur J Phys Rehabil Med. 2015;51(1):1–4.
16. Rehabilitation 2030. A call for action. Geneva: World Health Organization; 2017 (http://www.who.int/disabilities/care/rehab-2030/en/, accessed 28 February 2017).
17. Global cooperation on assistive technology (GATE). Geneva: World Health Organization; 2016 (http://www.who.int/phi/implementation/assistive_technology/phi_gate/en/, accessed 27 September 2016).
18. Khasnabis C, Mirza Z, MacLachlan M. Opening the GATE to inclusion for people with disabilities. Lancet 2015;386:2229–2230.
19. Tebbutt E, Brodmann R, Borg J, MacLachlan M, Khasnabis C, Horvath R. Assistive products and the sustainable development goals (SDGs). Global Health 2016;12:79.
20. Community-based rehabilitation: CBR guidelines. Geneva: World Health Organization; 2010 (http://www.who.int/disabilities/cbr/guidelines/en/, accessed 30 August 2016).
21. Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action. Geneva: World Health Organization; 2007 (http://www.who.int/healthsystems/strategy/everybodys_business.pdf, accessed 30 August 2016).

22. Alliance for Health Policy and Systems Research and World Health Organization. Systems thinking for health systems strengthening. Geneva: World Health Organization; 2009 (http://apps.who.int/iris/bitstream/10665/44204/1/9789241563895_eng.pdf?ua=1, accessed 30 December 2016).

23. Guidelines for training personnel in developing countries for prosthetics and orthotics services. Geneva: World Health Organization; 2005 (http://www.ispoint.org/sites/default/files/img/ispo-who_training_guidelines.pdf, accessed 30 August 2016).

24. Guidelines on the provision of manual wheelchairs in less-resourced settings. Geneva: World Health Organization; 2008 (http://www.who.int/disabilities/publications/technology/wheelchairguidelines/en/, accessed 30 August 2016).

25. Disclaimer on conflict of interest for the Standards Development Group Members of the WHO Standards for prosthetics and orthotics service provision:. Geneva: World Health Organization; 2017 (http://www.who.int/phi/implementation/assistive_technology/doi_sdg_posp.pdf?ua=1, accessed 24 April 2017).

26. Prosthetics and orthotics programme guide. Geneva: Landmine Survivors Network; 2006 (http://www.ispoint.org/sites/default/files/img/programme_guide_final_version.pdf, accessd 30 June 2016).

27. Physical rehabilitation programme: annual report 2013. Geneva: International Committee of the Red Cross; 2013 (https://shop.icrc.org/e-books/physical-rehabilitation-programme-annual-report-2013.html, accessed 30 June 2016).

28. World report on ageing and health. Geneva: World Health Organization; 2015 (http://www.who.int/ageing/publications/world-report-2015/en/, accessed 30 June 2016).

29. Briggs AM, Cross MJ, Hoy DG, Sànchez-Riera L, Blyth FM, Woolf AD, et al. Musculoskeletal health conditions represent a global threat to healthy aging: a report for the 2015 World Health Organization world report on ageing and health. Gerontologist 2016;56(Suppl 2):S243–S255.

30. Global status report on noncommunicable diseases 2010. Geneva: World Health Organization; 2011 (http://www.who.int/nmh/publications/ncd_report2010/en/, accessed 30 June 2016).

31. Global report on diabetes. Geneva: World Health Organization; 2016 (http://who.int/diabetes/global-report/en/, accessed 30 December 2016).

32. Diabetes atlas. Brussels: International Diabetes Federation; 2016 (http://www.idf.org/idf-diabetes-atlas-seventh-edition, accessed 30 August 2016).

33. Feigin VL, Mensah GA, Norrving B, Murray CJ, Roth GA, Group GSPE. Atlas of the global burden of stroke (1990–2013): the GBD 2013 study. Neuroepidemiology 2015;45:230–236.

34. Thrift AG, Cadilhac DA, Thayabaranathan T, Howard G, Howard VJ, Rothwell PM, et al. Global stroke statistics. Int J Stroke 2014;9:6–18.

35. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005;293:217–228.

36. Cavanagh PR, Lipsky BA, Bradbury AW, Botek G. Treatment for diabetic foot ulcers. Lancet 2005;366:1725–1735.

37. de Oliveira AL, Moore Z. Treatment of the diabetic foot by offloading: a systematic review. J Wound Care 2015;24:560, 2–70.

38. Cavanagh PR. Therapeutic footwear for people with diabetes. Diabetes Metab Res Rev 2004;20(Suppl 1):S51–S55.

39. Borg J, Lindström A, Larsson S. Assistive technology in developing countries: a review from the perspective of the Convention on the Rights of Persons with Disabilities. Prosthet Orthot Int 2011;35:20–29.

40. Keogh M. Dialogues on sustainable development: a disability inclusive perspective. Bensheim: CBM; 2015 (http://www.cbm.org/article/downloads/54741/CBM_Inclusive_Development_Dialogues_2015.pdf, accessed 30 June 2016).

41. Borg J, Östergren PO. Users' perspectives on the provision of assistive technologies in Bangladesh: awareness, providers, costs and barriers. Disabil Rehabil Assist Technol 2015;10:301–308.

42. Harkins CS, McGarry A, Buis A. Provision of prosthetic and orthotic services in low-income countries: a review of the literature. Prosthet Orthot Int 2013;37:353–361.

43. Prosthetics and orthotics project guide. Geneva: Landmine Survivors Network; 2006 (http://www.ispoint.org/sites/default/files/img/project_guide_final_version.pdf, accessed 30 June 2016).

44. Resolution 58.33. Sustainable health financing, universal coverage and social health insurance. In: Fifty Eighth World Health Assembly, Geneva, 25 May 2005. Resolution and decisions. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/20383/1/WHA58_33-en.pdf, accessed 25 April 2017).

45. Dobson A, El-Gamil A, Shimer M, DaVanzo JE. Economic value of prosthetic services among Medicare beneficiaries: a claims-based retrospective cohort study. Mil Med 2016;181(2 Suppl):18–24.

46. Resolution WHA 58.33. Sustainable health financing, universal coverage and social health insurance. In: Fifty-eighth World Health Assembly, Geneva, 16–25 May 2005. Resolutions and decisions. Geneva: World Health Organization; 2005 (http://apps.who.int/iris/bitstream/10665/20383/1/WHA58_33-en.pdf?ua=1, accessed 30 June 2016).

47. Szilagyi PG. Health insurance and children with disabilities. Future Child 2012;22:123–148.

48. Iezzoni LI, Frakt AB, Pizer SD. Uninsured persons with disability confront substantial barriers to health care services. Disabil Health J 2011;4:238–244.

49. Heinemann AW, Ehrlich-Jones L, Connelly L, Semik P, Fatone S. Enhancing quality of prosthetic services with process and outcome information. Prosthet Orthot Int 2016;41:164–170.

50. International Society for Prosthetics and Orthotics. ISPO consensus conference on appropriate orthopaedic technology for low-income countries: conclusions and recommendations. Prosthet Orthot Int 2001;25:168–170.

51. Jensen J, Sexton S. Appropriate prosthetic and orthotic technologies in low income countries (2000–2010). Brussels: International Society for Prosthetics and Orthotics; 2010 (http://www.ispoint.org/sites/default/files/archives/appropriate_prosthetic__orthotic_technologies_in_low_income_countries_2000-2010.pdf, accessed 30 June 2016).

52. ISO 8549-2: Prosthetics and orthotics – Vocabulary – Part 2: Terms relating to external limb prostheses and wearers of these prostheses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15801, accessed 11 January 2017).

53. ISO 8549-3: Prosthetics and orthotics – Vocabulary – Part 3: Terms relating to external orthoses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15802, accessed 11 January 2017).

54. ISO 13405: Prosthetics and orthotics – Classification and description of prosthetic components. Parts 1, 2 and 3. Geneva: International Organization for Standardization; 2015.

55. Resolution 67.20. Regulatory system strengthening for medical products. In: Sixty seventh World Health Assembly, Geneva, 24 May 2014. Resolution and decisions. Geneva: World Health Organization; 2014 (http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf?ua=1, accessed 30 August 2016).

56. Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) quality standards. Baltimore, MD: Centres for Medicare and Medicaid Services, 2008.

57. ISO 22523:2006. External limb prostheses and external orthoses. Requirements and test methods. Geneva: International Organization for Standardization; 2006 (http://www.iso.org/iso/catalogue_detail.htm?csnumber=37546, accessed 30 June 2016).

58. WHO compendium of innovative health technologies for low-resource settings. Geneva: World Health Organization; 2015 (http://www.who.int/medical_devices/innovation/compendium/en/, accessed 30 June 2016).

59. Körner M, Bütof S, Müller C, Zimmermann L, Becker S, Bengel J. Interprofessional teamwork and team interventions in chronic care: a systematic review. J Interprof Care 2016;30:15–28.

60. Nancarrow SA, Booth A, Ariss S, Smith T, Enderby P, Roots A. Ten principles of good interdisciplinary team work. Hum Resources Health 2013;11:19.

61. Clarke DJ, Forster A. Improving post-stroke recovery: the role of the multidisciplinary health care team. J Multidiscip Healthcare 2015;8:433–442.

62. Meyer MJ, Teasell R, Thind A, Koval J, Speechley M. A synthesis of peer-reviewed literature on team-coordinated and delivered early supported discharge after stroke. Can J Neurol Sci 2016;43:353–359.

63. Knowlton LM, Gosney JE, Chackungal S, Altschuler E, Black L, Burkle FM, et al. Consensus statements regarding the multidisciplinary care of limb amputation patients in disasters or humanitarian emergencies: report of the 2011 Humanitarian Action Summit Surgical Working Group on amputations following disasters or conflict. Prehosp Disaster Med 2011;26:438–448.

64. Tavernaro M, Pellegrini A, Tessadri F, Zaina F, Zonta A, Negrini S. Team care to cure adolescents with braces (avoiding low quality of life, pain and bad compliance): a case–control retrospective study. Scoliosis 2012;7:17.

65. Negrini S, Aulisa AG, Aulisa L, Circo AB, de Mauroy JC, Durmala J, et al. 2011 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis 2012;7:3.

66. Transforming and scaling up professionals' education and training. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/93635/1/9789241506502_eng.pdf, accessed 30 June 2016).

67. Category I professional – Prosthetist/orthotist, orthopaedic engineer, orthopaedic meister. Brussels: International Society for Prosthetics and Orthotics; 2007 (http://www.ispoint.org/sites/default/files/archives/information_package_cat_1_aug2007.pdf, accessed 30 December 2016).

68. Category II professional – Orthopaedic technologist. Brussels: International Society for Prosthetics and Orthotics; 2010 (http://www.ispoint.org/sites/default/files/archives/category_ii_english_may2010.pdf, accessed 30 June 2016).

69. Category III professional – Prosthetic/orthotic technician. Brussels: International Society for Prosthetics and Orthotics; 2001 (http://www.ispoint.org/sites/default/files/archives/category_iii_english_jan01.pdf, accessed 30 December 2016).

70. Standards and guidelines for the accreditation of educational programs in orthotics and prosthetics. Alexandria, VA: National Commission on Orthotic and Prosthetic Education; 2010.

71. Aminian G, O'Toole JM. Undergraduate prosthetics and orthotics programme objectives: a baseline for international comparison and curricular development. Prosthet Orthot Int 2011;35:445–450.

72. Aminian G, O'Toole JM, Mehraban AH. Undergraduate prosthetics and orthotics teaching methods: a baseline for international comparison. Prosthet Orthot Int 2015;39:278–285.

73. Cochrane H, Rosario D, Singh A, Ghosh R. Prosthetics and orthotics impact assessment: India and Bangladesh. Brussels: International Society for Prosthetics and Orthotics; 2015 (http://www.ispoint.org/sites/default/files/india_bangladesh_ispo_impact_assessment_report_low_resolution.pdf, accessed 30 December 2016).

74. Fisk J, Soderberg B, Trebbin H, Cochrane H, Stills M. ISPO/LWVF evaluation team VIETCOT graduates report. Copenhagen: International Society for Prosthetics and Orthotics; 2010 (http://www.ispoint.org/sites/default/files/sections/partnership/vietnam_final_report_feb_2011.pdf, accessed 30 August 2016).

75. Sexton S, Shangali H, Munissi B. Prosthetics and orthotic impact assessment: the impact of training personnel to the minimum standards ISPO Category I and II (East Africa: Tanzania, Kenya and Uganda). Brussels: International Society for Prosthetics and Orthotics; 2013 (http://www.ispoint.org/sites/default/files/sections/partnership/ispo_impact_assessment_tatcoteast_africa_with_appendices.pdf, accessed 30 August 2016).

76. Sexton S, Jovane R, Rosario D, Castaneda M. Prosthetics and orthotics impact assessment: Latin America: Mexico, Guatemala and Colombia. Brussels: International Society for Prosthetics and Orthotics; 2015 (http://www.ispoint.org/sites/default/files/mexico_guatemala_colombia_ispo_impact_assessment_report_low_resolution.pdf, accessed 30 August 2016).

77. Sexton S, Stills M, Chhoeurn V, Kheng S. Prosthetics and orthotic impact assessment. South East Asia: Cambodia and Lao PDR. Brussels: International Society for Prosthetics and Orthotics; 2015 (http://www.ispoint.org/sites/default/files/cambodia_laos_ispo_impact_assessment_report_low_resolution.pdf, accessed 30 June 2016).

78. Tardif C, Niang M, Amah A. Prosthetics and orthotics impact assessment West Africa: Togo and Benin. Brussels: International Society for Prosthetics and Orthotics; 2016 (http://www.ispoint.org/sites/default/files/benin_and_togo_ispo_impact_assessment_report_low_resolution_english.pdf, accessed 30 December 2016).

79. Forghany S, Sadeghi-Demneh E, Trinler U, Onmanee P, Dillon MP, Baker R. The influence of staff training and education on prosthetic and orthotic service quality: a scoping review. Prosthet Orthot Int; In Press.

80. ISPO education standard for prosthetic/orthotic occupations (draft). Brussels: International Society for Prosthetics and Orthotics, 2016.

81. Amputee rehabilitation guidance for the education of pre registration physiotherapy students. London: British Association of Chartered Physiotherapists in Amputee Rehabilitation; 2013 (http://bacpar.csp.org.uk/publications/amputee-rehabilitation-guidance-education-pre-registration-physiotherapy-studen, accessed 30 June 2016).

82. Undergraduate medical education in rehabilitation medicine. London: British Society of Rehabilitation Medicine; 2006 (http://www.bsrm.org.uk/downloads/printcopy21-06-06-mk2-security.pdf, accessed 30 June 2016).

83. Geertzen JH, Rommers GM, Dekker R. An ICF-based education programme in amputation rehabilitation for medical residents in the Netherlands. Prosthet Orthot Int 2011;35:318–22.

84. Evidence based clinical guidelines for the physiotherapy management of adults with lower limb prostheses. London: British Association of Chartered Physiotherapists in Amputee Rehabilitation; 2012 (http://www.csp.org.uk/sites/files/csp/secure/bacpar_amputee_rehab_guidelines_2012_1.pdf, accessed 30 June 2016).

85. Amputee and prosthetic rehabilitation – standards and guidelines. London: British Society of Rehabilitation Medicine; 2003 (http://www.bsrm.org.uk/downloads/ars-gfinaltext.pdf, accessed 30 June 2016).

86. International Society for Prosthetics and Orthotics. ISPO consensus conference on poliomyelitis: consensus statements. Prosthet Orthot Int. 2001;25(3):171–180.

87. Report of a consensus conference on the orthotic management of stroke patients. Copenhagen: International Society for Prosthetics and Orthotics; 2003 (https://drive.google.com/file/d/0ByJx_BNVaM-eTldaMXNXMjNrSnc/view, accessed 30 June 2016).

88. Morris C, Condie D, Fisk J. ISPO cerebral palsy consensus conference report. Prosthet Orthot Int 2009;33(4):401–402.

89. Kilbride C. Splinting for the prevention and correction of contractures in adults with neurological dysfunction: practice guideline for occupational therapists and physiotherapists. London: College of Occupational Therapists; Association of Chartered Physiotherapists in Neurology; 2015.

90. Magnusson L, Ramstrand N. Prosthetist/orthotist educational experience and professional development in Pakistan. Disabil Rehabil Assist Technol 2009;4:385–392.

91. Magnusson L, Ahlström G. Experiences of providing prosthetic and orthotic services in Sierra Leone – the local staff's perspective. Disabil Rehabil 2012;34:2111–2118.

92. Magnusson L, Shangali H, G A. Graduates' perceptions of prosthetic and orthotic education and clinical practice in Tanzania and Malawi. Afr J Disabil 2016;5:a142.

93. DaVanzo JE, El-Gamil A, Heath S, Pal S, Li J, Luu PH, et al. Projecting the adequacy of workforce supply to meet patient demand: analysis of the orthotics and prosthetics (O&P) profession. Vienna, VA: LLC; Dobson DaVanzo & Associates; 2015.

94. Seccombe I, Stock J. The labour market for qualified orthotists/prosthetists. Health Trends 1994;26:53–56.

95. Ridgewell E, Dillon M, O'Connor J, Anderson S, Clarke L. Demographics of the Australian orthotic and prosthetic workforce 2007. Aust Health Rev 2016;40:555–561.

96. Guidance paper on the supervision of assistant practitioners, BAPO standards for best practice. Paisley, Renfrewshire: British Association of Prosthetists and Orthotists; 2013 (https://www.bapo.com/Framework/ResourceManagement/GetResourceObject.aspx?ResourceID=039ddb45-d3be-4b2d-9a26-0e3ff593b0a0, accessed 30 June 2016).

97. Increasing access to health workers in remote and rural areas thorugh improved retention. Geneva: World Health Organization; 2010 (http://apps.who.int/iris/bitstream/10665/44369/1/9789241564014_eng.pdf, accessed 30 December 2016).

98. Skempes D, Bickenbach J. Strengthening rehabilitation for people with disabilities: a human rights approach as the essential next step to accelerating global progress. Am J Phys Med Rehabil 2015;94:823–828.

99. American Geriatrics Society Expert Panel on Person-centered Care. Person-centered care: a definition and essential elements. J Am Geriatr Soc 2016;64:15–18.

100. Healy A, Farmer S, Pandyan A, Chockalingam N. Effectiveness and cost–effectiveness of prosthetic and orthotic interventions: a systematic review. Centre for Reviews and Dissemination. York: University of York; 2016; CRD42016025994.

101. The relationship between prosthetics and orthotic services and community based rehabilitation. A joint ISPO/WHO statement. October 1999. Prosthet Orthot Int 1999;23:189–194 (http://poi.sagepub.com/content/23/3/189.full.pdf, accessed 30 June 2016).

102. Physical rehabilitation centres: architectural programming handbook. Geneva: International Committee of the Red Cross; 2015 (https://shop.icrc.org/e-books/icrc-activities-ebook/physical-rehabilitation-centres-handbook.html, accessed 30 June 2016).

103. Negrini S, Donzelli S, Lusini M, Minnella S, Zaina F. The effectiveness of combined bracing and exercise in adolescent idiopathic scoliosis based on SRS and SOSORT criteria: a prospective study. BMC Musculoskelet Disord 2014;15:263.

104. Boddington M, Kaphingst W, Massoud R, Stills M, Trebbin H, Verhoeff T. Planning, monitoring and evaluation of P&O programmes. Copenhagen: International Society for Prosthetics and Orthotics, 2004.

105. Bosmans J, Geertzen J, Dijkstra PU. Consumer satisfaction with the services of prosthetics and orthotics facilities. Prosthet Orthot Int 2009;33:69–77.

Annex 1. Summary of standards

Area 1. Policy

Leadership and governance

Stakeholders and coordination

1	Governments should assume a leading role in the development and coordination of national prosthetics and orthotics service provision.
2	Governments should involve all relevant stakeholders – including service users, caregivers and user groups – in policy development, planning, implementation, monitoring and evaluating prosthetics and orthotics services.
3	A national prosthetics and orthotics committee or similar entity, with a wide range of stakeholders, should be in place for the coordination and development of national prosthetics and orthotics service provision.

Guiding framework for prosthetics and orthotics service provision

4	There should be a national guiding framework for prosthetics and orthotics service provision.
5	Prosthetics and orthotics service provision should be regulated by the State.

Monitoring

6	Prosthetics and orthotics service should be monitored nationally and regionally.

International coordination and cooperation

7	Governments and national stakeholders should collaborate internationally and share experience, data and research on prosthetics and orthotics service provision.

International support

8	International support, when provided, should contribute to the establishment and implementation of national prosthetics and orthotics policies and strategic plans and be aligned with the provision system of the national health and welfare service.

Financing

Economic analysis of prosthetics and orthotics service provision

9	The cost of providing prosthetics and orthotics services should be assessed periodically.
10	The direct and indirect economic benefits of prosthetics and orthotics services should be analysed at individual, family, community, society, health sector and national levels.

Funding prosthetics and orthotics services

11	Prosthetics and orthotics services should be an integral part of universal health coverage.
12	Prosthetics and orthotics services should be included in national health and social insurance systems, like other health interventions.

Information

13	Data on prosthetics and orthotics service provision should be collected periodically, analysed at service level and shared at national level.
14	A national prosthetics and orthotics database should be established to identify total need, types of need and unmet need.

Promotion of prosthetics and orthotics services

15	Strategies for raising awareness about prosthetics and orthotics services should be established, including rights-based, social and economic arguments.

Area 2. Products

Types

16	An appropriate range of prosthetic and orthotic products should be available in countries to suit local needs and realities.
17	A national list of priority prosthetic and orthotic products should be drawn up, respected and updated regularly.
18	International standards should be used for national classification of prosthetic and orthotic products.

Supply of materials

19	Components, materials, consumables, tools, machines and other equipment used exclusively for fabrication of prosthetic and orthotic products that are not available in a country should be exempt from import duty and customs fees.
20	Reuse of prosthetic and orthotic components should be regulated by a designated authority or group of experts with no conflict of interests and involve proper quality control and documentation.

Technical standards

21	National regulation of prosthetic and orthotic products, components and materials should be an integral part of the national health care regulatory system.
22	Prosthetic and orthotic products should be tested structurally for compliance with ISO or equivalent standards before being sold on the market.

Research and development

23	Clinical and technical research should be conducted in prosthetics and orthotics, and the results should be shared nationally and globally.
24	Affordable prosthetic and orthotic products that are cost–effective, of good quality and context-appropriate should be developed and made widely available.

Area 3. Personnel

Personnel who provide prosthetics and orthotics services

25 Prosthetics and orthotics services should be provided by competent, adequately trained professionals.

26 Complicated prosthetics and orthotics treatment and care of complex cases should be provided by a multidisciplinary team of professionals with complementary skills.

Training in prosthetics and orthotics

Core personnel

27 Training in prosthetics and orthotics should be aligned with national and international educational standards.

28 Training in prosthetics and orthotics should be available at various levels to fully meet national needs.

Other personnel

29 Health care professionals, especially rehabilitation professionals, who provide treatment relevant to prosthetics and orthotics services should have adequate knowledge about prosthetics and orthotics.

Continuing professional development

30 Continuing professional development should be compulsory in prosthetics and orthotics professional practice.

Planning the prosthetics and orthotics workforce

31 Workforce planning should take into account all the disciplines required in prosthetics and orthotics services at all levels.

32 Prosthetics and orthotics service units should have at least one prosthetist and orthotist to supervise and guide clinical and technical work.

33 A strategy to retain prosthetics and orthotics personnel should be in place.

Professional regulation and recognition

34 Prosthetics and orthotics clinicians should be regulated by the State within regulations for health professionals.

35 Prosthetists and orthotists should assume responsibility for services provided by associate and nonclinical personnel under their supervision.

36 Prosthetics and orthotics personnel should have a clear career structure and employment conditions that are aligned with those of other health care professionals, associates and technical personnel.

Area 4. Provision of services

User-centred service delivery

37	A documented policy to safeguard the rights of users of prosthetics and orthotics services should be in place and in effect, outlining the features of user-centred services.
38	Service users and their representatives should be involved in policy-making, planning, implementing, monitoring and evaluating prosthetics and orthotics services, take part in decision-making at all levels and be represented on relevant committees.
39	Service users should be given the opportunity to choose their service provider and technology, including components and materials, according to their need, among the options available in the country and the limits set for financing or reimbursement.

Systems for delivering services

Inclusive service delivery

40	Prosthetics and orthotics services should be accessible to all the people who need them: girls, boys, women, men and older adults.
41	Prosthetics and orthotics services should be part of the health sector or be closely linked to it.
42	Prosthetics and orthotics services should be delivered in a three-tier system, at primary, secondary and tertiary levels, with established links and two-way pathways for referral and follow-up.
43	Maintenance and repair services should be an integral part of a prosthetics and orthotics service delivery system.

Inclusive service delivery in disaster contexts

44	The provision of prostheses and orthoses in disaster conditions should be an integral part of the health sector response and be planned to ensure a seamless transition to long-term service provision.

Service units

Setting

45	Prosthetics and orthotics service units should be established within or closely linked to health and rehabilitation service facilities, such as district and referral hospitals.
46	The possibility of integrating prosthetics and orthotics service units into broader services for assistive products should be considered and explored.

Infrastructure

47	At all service levels, prosthetics and orthotics units should be designed to ensure effective, efficient, high-quality service provision in a user-friendly, barrier-free, safe clinical environment.

Equipment

48	Prosthetics and orthotics service providers should define and adhere to a plan for equipment maintenance and replacement.

Safety

49	The safety of service providers and users should be ensured by the establishment of documented health and safety regulations.

Service units processes

The service delivery process

Identification and referral

50 Prosthetics and orthotics service providers should identify and train partners in identifying and referring potential users.

Service delivery

51 All steps in the delivery of prosthetics and orthotics services should be based on the best available evidence and should adhere to local, national and international standards and practice.

Assessment

52 Service providers should involve service users and caregivers in assessment, setting goals and planning treatment.

53 Peer support and counselling should be available to service users as appropriate.

Fabrication and fitting

54 Prosthetics and orthotics personnel should follow the instructions and guidelines of the component manufacturer and document any deviation from standard practice.

User training

55 Service users should be given sufficient training to ensure safe, effective use of prostheses and orthoses. Family members and caregivers should be involved as appropriate.

Product delivery and follow-up

56 Users or caregivers should make the final decision about the acceptability of the fit and function of the prosthesis or orthosis.

57 The outcome of prosthetics and orthotics treatment should be evaluated and documented.

58 Prosthetics and orthotics service users should be followed up regularly.

Management

59 Annual and long-term strategic and operational plans should be in place, with performance indicators for continuous monitoring.

60 The required quality should be defined and adhered to at all levels and in all parts of the prosthetics and orthotics service delivery system.

Notes

Notes

POLICY

PRODUCTS

PERSONNEL

PROVISION

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