STANDARDS FOR PROSTHETICS AND ORTHOTICS

Part 1: STANDARDS
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WHO standards for prosthetics and orthotics


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Contributors

**WHO steering group**
Alarcos Cieza, Pauline Kleinitz, Maryam Mallick, Satish Mishra, Zafar Mirza, Andrea Pupulin, Hala Sakr, Emma Tebbutt, and Armando Jose Vasquez

**Standards development group**
Girma Bireda Assena, Josephine Bundoc, Mary Anne Burke, Bishnu Maya Dhungana, Elaine Figgins, Ritu Ghosh, Allen Ingersoll, Ev Innes, Friedbert Kohler, Malcolm MacLachlan (Chair), William Neumann, Teap Odom, Wesley Pryor, Youssef Salam, Daniel Suarez, Claude Tardif and Nils-Odd Tønnevold

**External review group**

**Executive editor**
Chapal Khasnabis

**Lead authors**
Anders Eklund and Sandra Sexton

**Additional contributions**

**Systematic reviewers**
First review group led by Nachiappan Chockalingam and Aoife Healy. Second review group led by Richard Baker, Saeed Forghany and Ebrahim Sadeghi-Demneh

**Technical editing**
Elisabeth Heseltine

**Proof-reading**
Diane Bell and Angela Weatherhead

**Cover photography**
China Assistive Devices and Technology Center for Persons with Disabilities, Mobility India and Royal National Orthopaedic Hospital-UK

**Partner organizations**
International Society for Prosthetics and Orthotics and United States Agency for International Development

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Wendy Hamzai and Rachel McLeod-MacKenzie
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).
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.
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).
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).
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.

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**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.

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**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 through 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).
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.

<table>
<thead>
<tr>
<th>Area</th>
<th>Challenge</th>
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<tbody>
<tr>
<td><strong>Policy</strong></td>
<td>• Absence of policies and national plans for prosthetics and orthotics, rehabilitation and assistive technology in most countries</td>
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<tr>
<td></td>
<td>• Lack of awareness and understanding about the role, purpose and benefits of prosthetics and orthotics services</td>
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<td></td>
<td>• Limited funding, as these services are frequently not included in national health and social insurance systems</td>
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<td></td>
<td>• Limited data on needs for these services, making it difficult to understand the practical and financial requirements of providing such services for all</td>
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<tr>
<td><strong>Products</strong></td>
<td>• Limited availability of appropriate products in many countries</td>
</tr>
<tr>
<td></td>
<td>• High price of high-quality prostheses and orthoses. Even low-cost alternatives may be perceived as expensive, particularly in low- and middle-income countries.</td>
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<tr>
<td></td>
<td>• Lack of national product standards in many countries, often resulting in devices that do not meet acceptable safety standards</td>
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<tr>
<td></td>
<td>• Limited evidence of the effectiveness and cost–effectiveness of products, technologies and working methods</td>
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<tr>
<td><strong>Personnel</strong></td>
<td>• Lack of qualified personnel, reducing the quality and quantity of services. Available personnel are usually found in large cities.</td>
</tr>
<tr>
<td></td>
<td>• Limited access to schools and training opportunities for prosthetics and orthotics</td>
</tr>
<tr>
<td><strong>Provision of</strong></td>
<td>• Unequal service provision. Services are frequently available only in capital and other large cities and not to poor, isolated populations in rural areas.</td>
</tr>
<tr>
<td><strong>services</strong></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Prosthetics and orthotics services are frequently perceived as an expense rather than an investment.</td>
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</table>

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.”
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.

<table>
<thead>
<tr>
<th>NO.</th>
<th>STANDARD</th>
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<tbody>
<tr>
<td>1</td>
<td>Governments should assume a leading role in the development and coordination of national prosthetics and orthotics service provision.</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

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<tr>
<th>NO.</th>
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<tbody>
<tr>
<td>4</td>
<td>There should be a national guiding framework for prosthetics and orthotics service provision.</td>
</tr>
<tr>
<td>5</td>
<td>Prosthetics and orthotics service provision should be regulated by the State.</td>
</tr>
</tbody>
</table>

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.

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<tr>
<th>NO.</th>
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<tr>
<td>6</td>
<td>Prosthetics and orthotics service should be monitored nationally and regionally.</td>
</tr>
</tbody>
</table>

Related topics in the implementation manual:
1C Monitoring
10 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.

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

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.

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<tbody>
<tr>
<td>11</td>
<td>Prosthetics and orthotics services should be an integral part of universal health coverage.</td>
</tr>
<tr>
<td>12</td>
<td>Prosthetics and orthotics services should be included in national health and social insurance systems, like other health interventions.</td>
</tr>
</tbody>
</table>

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.

Related topics in the implementation manual:
IN Assessing the need
IO Collection of data
IP 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.

Related topics in the implementation manual:
IQ Awareness-raising
IR Strengthening the image
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.”
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.
An appropriate range of prosthetic and orthotic products should be available in countries to suit local needs and realities.

A national list of priority prosthetic and orthotic products should be drawn up, respected and updated regularly.

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.

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.

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.
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.
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.
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 non-clinicians, continues to largely exceed the supply. More transformative training and education are required to address the need. 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. 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. 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. 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 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.

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. This will maintain the quality and efficiency of services and ensure that investment in training has its intended long-term impact.

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<tbody>
<tr>
<td>31</td>
<td>Workforce planning should take into account all the disciplines required in prosthetics and orthotics services at all levels.</td>
</tr>
<tr>
<td>32</td>
<td>Prosthetics and orthotics service units should have at least one prosthetist and orthotist to supervise and guide clinical and technical work.</td>
</tr>
<tr>
<td>33</td>
<td>A strategy to retain prosthetics and orthotics personnel should be in place.</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>No.</th>
<th>Standard</th>
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<tr>
<td>34</td>
<td>Prosthetics and orthotics clinicians should be regulated by the State within regulations for health professionals.</td>
</tr>
<tr>
<td>35</td>
<td>Prosthetists and orthotists should assume responsibility for services provided by associate and nonclinical personnel under their supervision.</td>
</tr>
<tr>
<td>36</td>
<td>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.</td>
</tr>
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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.

_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.”_
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 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”.

23
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.

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.

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<tr>
<td>40</td>
<td>Prosthetics and orthotics services should be accessible to all the people who need them: girls, boys, women, men and older adults.</td>
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<tr>
<td>41</td>
<td>Prosthetics and orthotics services should be part of the health sector or be closely linked to it.</td>
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<tr>
<td>42</td>
<td>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.</td>
</tr>
<tr>
<td>43</td>
<td>Maintenance and repair services should be an integral part of a prosthetics and orthotics service delivery system.</td>
</tr>
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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.

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<tr>
<td>44</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

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

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.

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

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<th>Service delivery steps</th>
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<tbody>
<tr>
<td>1. Assessment</td>
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<tr>
<td>2. Fabrication and fitting</td>
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<tr>
<td>3. User training</td>
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<tr>
<td>4. Product delivery and follow-up</td>
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</table>

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.
**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).

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<tr>
<td>59</td>
<td>Annual and long-term strategic and operational plans should be in place, with performance indicators for continuous monitoring.</td>
</tr>
<tr>
<td>60</td>
<td>The required quality should be defined and adhered to at all levels and in all parts of the prosthetics and orthotics service delivery system.</td>
</tr>
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</table>

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.”
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.”
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# 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.
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Part 2: IMPLEMENTATION MANUAL
STANDARDS FOR PROSTHETICS AND ORTHOTICS

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Contributors

**WHO steering group**
Alarcos Cieza, Pauline Kleinitz, Maryam Mallick, Satish Mishra, Zafar Mirza, Andrea Pupulin, Hala Sakr, Emma Tebbutt, and Armando Jose Vásquez

**Standards development group**
Girma Bireda Assena, Josephine Bundoc, Mary Anne Burke, Bishnu Maya Dhungana, Elaine Figgins, Ritu Ghosh, Allen Ingersoll, Ev Innes, Friedbert Kohler, Malcolm MacLachlan (Chair), William Neumann, Teap Odom, Wesley Pryor, Youssef Salam, Daniel Suarez, Claude Tardif and Nils-Odd Tønnevold

**External review group**

**Executive editor**
Chapal Khasnabis

**Lead authors**
Anders Ekland and Sandra Sexton

**Additional contributions**

**Systematic reviewers**
First review group led by Nachiappan Chockalingam and Aoife Healy. Second review group led by Richard Baker, Saeed Forghany and Ebrahim Sadeghi-Demneh

**Technical editing**
Elisabeth Heseltine

**Proof-reading**
Diane Bell and Angela Weatherhead

**Cover photography**
China Assistive Devices and Technology Center for Persons with Disabilities, Mobility India and Royal National Orthopaedic Hospital-UK

**Partner organizations**
International Society for Prosthetics and Orthotics and United States Agency for International Development

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Abbreviations and acronyms

ASCENT  Amputee Screening through Cellphone Networking
CBR    community-based rehabilitation
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
MSA  medical savings account
NGO  nongovernmental organization
PHC  primary health care
SDG  Sustainable Development Goal
USAID  United States Agency for International Development
VAT  value added tax

The four key areas of health systems
Introduction

Purpose of the manual

WHO, in partnership with the International Society for Prosthetics and Orthotics (ISPO) and the United States Agency for International Development (USAID), has prepared prosthetics and orthotics standards to guide Member States in improving access to high-quality, affordable prosthetics and orthotics services, presented in Part 1 of this publication. For more detailed instructions on “what, why, how, who and when” for each standard, WHO also prepared this implementation manual. The main purpose of the manual is to support Member States in analysing the situation of prosthetics and orthotics services in their countries, which, in turn, helps setting priorities for implementation of the standards. The manual provides advice on planning, implementing, managing and developing or improving prosthetics and orthotics services to meet the proposed standards. It is designed to stimulate discussion on the wide range of issues to be considered in preparing policies and strategic plans and establishing benchmarks for services. It promotes planning, goal-setting, implementation and monitoring of services as a joint effort of governments and national stakeholders.

Scope and structure

Like the document on standards, the manual covers the four core areas of prosthetics and orthotics service: policy (governance, financing and information), products (prostheses and orthoses), personnel (workforce) and provision of services. Although some sections are linked, each can be read independently to obtain limited or more specific information. Several topics are illustrated with brief country examples.

The manual presents the different aspects of prosthetics and orthotics services but does not provide enough detail to serve as a blueprint for service implementation in all countries. Plans and priorities differ among and even within countries, depending on the context and the resources that can be made available.
Stakeholders and their roles

Many different stakeholders with specific, complementary skills and resources are required to establish, strengthen and maintain a well-functioning, effective prosthetics and orthotics service, including:

• users, families and caregivers;
• user groups and disabled people’s organizations;
• national, regional and local governments;
• civil society organizations;
• both public and private prosthetics and orthotics service providers;
• 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.

Service users, families and caregivers

Service users must be at the centre of planning, implementation, monitoring and evaluation of prosthetics and orthotics services. Not only is this their right, but they are an indispensable resource in this work (see 4B). Service users should be empowered to engage actively in service provision, as individuals or as representatives of their organizations.
When people have severe physical impairments and rely on assistance for day-to-day activities, it is important to involve family members, caregivers and others to provide their perspective on service provision.

**User groups and disabled people’s organizations**

These groups can participate on behalf of users in planning, implementing, monitoring and evaluating programmes and may also represent the interests of users on advisory committees. These organizations often have a wide geographical reach, so that they make important contributions to awareness-raising and to the identification and referral of potential users. With the necessary instructions and training, they can work with service providers in peer counselling, follow-up of individuals, collection of user feedback and impact assessments.

**Governments**

According to the Convention on the Rights of Persons with Disabilities (CRPD), it is the responsibility of governments to promote the availability and use of high-quality assistive devices and technologies, including prostheses and orthoses, at an affordable cost (1). Governments need not be involved in direct service delivery, but the State – represented by various ministries – is obliged to enact legislation, formulate policy, prepare national plans, regulate, finance, raise awareness and generally support and promote prosthetics and orthotics. Governments can create the circumstances for services to flourish in both the private and the public sector and bring together the relevant stakeholders. For this purpose, a national prosthetics and orthotics committee or similar entity could be established within structures for the coordination of health, rehabilitation and assistive technology (see Box 1).

---

**Box 1. A national prosthetics and orthotics committee**

Coordination of prosthetics and orthotics services is strengthened by the creation of a national prosthetics and orthotics committee or similar entity. This body is best established within existing structures for the coordination of health, rehabilitation and assistive technology, perhaps as a subgroup of a broader entity, as long as sufficient attention is given to the details of prosthetics and orthotics. The structure will depend on the local context. In India, for example, a prosthetics and orthotics committee has been established within the Rehabilitation Council of India to support education on these specialties and service delivery.

A committee with varied membership and a prominent role for the government can coordinate the development of national policies, legislation and strategic plans and monitor services, to ensure that all stakeholders are working towards the same goals. To be effective, the committee should set clear aims and objectives for its work and meet regularly, as required by the local situation.

Although many tasks can be delegated by incorporating self-governance and professional stewardship, the involvement of relevant government offices, at both national and local levels, may still be required. To give appropriate attention to the sector, governments could establish an office dedicated to rehabilitation and assistive technology, coordinated by professional experts.
Civil society organizations
Civil society organizations are important in prosthetics and orthotics services, as they work with local populations and can help to raise awareness and increase the uptake of treatment by geographically and culturally diverse populations. Their voices are often the motivation for policy development and practice.

Prosthetics and orthotics service providers
Service providers, who may be public, private (profit or non-profit), nongovernmental or philanthropic (see 4E), not only provide direct services but have a significant responsibility for collecting data for national planning.

Health and rehabilitation services
These services are critical to successful prosthetics and orthotics service provision, and prosthetics and orthotics services are an important component of the health and rehabilitation continuum (see 4F and 4G). The involvement of representatives of health and rehabilitation services is therefore essential in all phases of planning and service development.

Training and academic institutions
National and regional training institutions can ensure that sufficient numbers of competent prosthetics and orthotics personnel are available to meet the needs of the country. They are also central to initiating, conducting and promoting research. Training institutions must be directly involved in workforce planning (see 3H) and sector planning so that the training issues are well understood and the need for trained personnel is taken into account and met in a timely manner. In countries where there are no prosthetics or orthotics schools, advice may be sought from schools and academic institutions in neighbouring countries.

Professional associations
Associations of prosthetists and orthotists, physiotherapists, occupational therapists, nurses, doctors and other disciplines have collective knowledge that is indispensable for the planning, development and promotion of prosthetics and orthotics services. Valuable additional support can also be provided by regional and international associations.

Manufacturers and suppliers of components, materials and consumables
Manufacturers and suppliers should conduct research on, develop, produce, make available and provide training in good-quality, cost-effective components and materials for the fabrication of prostheses and orthoses for the full range of treatment in various contexts.

International organizations and agencies
The international prosthetics and orthotics community has an important role in advocacy, international coordination and exchange of information as well as in the provision of direct technical support and funding for prosthetics and orthotics development (see 1D).
Funding agencies
If prosthetics and orthotics services are to be affordable for all persons in need, they cannot rely solely on out-of-pocket payments. In most countries, services can be sustained only if they are subsidized by government funds, insurance, charities, corporate social responsibility schemes and other sources (see 1J and 1K).

1B Guiding framework
Governments are responsible for establishing a guiding framework for prosthetics and orthotics services, including national laws, policies, plans, standards, regulations and rules for licensing service providers and for accreditation of prosthetists and orthotists and their associates. The framework should be developed and monitored in collaboration with all national stakeholders.

Legislation
The CRPD, which can serve as a template for formulating national laws and policies, stipulates that governments should adopt the necessary legislative measures to assure recognized rights (1). Most countries have laws assuring the rights of people with disabilities, but national legislation might have to be revised and updated. Governments are equally obliged to make sure that the laws are enforced.

Policy
Governments, in collaboration with other stakeholders, should formulate a policy for prosthetics and orthotics services, clearly setting out general principles for the development and functioning of the services. The policy should ensure that services are affordable, accessible, effective, efficient, safe and of acceptable quality and adhere to international standards. As appropriate in the country context, the policy should be integrated into a broader policy for rehabilitation and/or assistive technology, if the specifics of prosthetics and orthotics are adequately addressed.

National plan
A national strategic plan for prosthetics and orthotics services should be an integral component of a national health strategy and linked to national development plans. It should set detailed goals and concrete steps for establishing, developing and managing such services. A national plan prepared by all relevant stakeholders can function as a working document, providing a brief outline of the structures and functions of the service system, and can gradually incorporate more information, with detailed plans, processes and standards. The plan may address most of the areas covered in this manual. Each requires separate discussion but all are interrelated and will have greater impact when linked within a comprehensive plan.

Standards
Governments, in collaboration with stakeholders, should define standards for working methods, processes, practices, infrastructure and equipment in prosthetics and orthotics
services. The standards should be framed so that they can be applied to monitoring, auditing and evaluation of each aspect of services. International standards, such as those in Part 1 of this publication and those of the International Organization for Standardization (ISO) can serve as models for preparing national standards. The ISO standards include those for the provision of prosthetics, orthotics and assistive devices, for rehabilitation (2-5) and general quality standards (ISO 9000 on the fundamentals of quality management systems and ISO 9001 on the requirements for meeting the standard).

**Regulation**

To protect the interests and safety of users, regulation should ensure services are provided in a professional manner by adequately trained personnel following correct procedures and using reliable materials and equipment. The regulation of prosthetics and orthotics services should be an integral part of the national health care regulatory system (6), to be established by governments in collaboration with relevant stakeholders. To ensure a solid foundation for appropriate, safe service delivery, governments should regulate, for example:

- prosthetics and orthotics training;
- prosthetists, orthotists and their associates (usually as part of regulations on health professionals, see 3J);
- prosthetics and orthotics services (as part of licensing, see below);
- prosthetic and orthotic products (as part of regulation of health products, see 2G);
- use of prosthetic and orthotic components and materials (usually as part of regulation of the products);
- the importation and distribution of prosthetic and orthotic components, materials, prefabricated products, tools, machines and other equipment (as part of customs regulations, see 2F and 2G);
- financing of prosthetics and orthotics services (see 1K); and
- the issuance of purchase requisitions (as part of financing of services).

Mechanisms should be established for implementation, monitoring and enforcement. Monitoring is usually conducted by a government office, but responsibility may be delegated to an independent agency. Enforcement may include legal proceedings. A certain degree of self-regulation may be applied, such that service providers monitor their own adherence to national standards.

**Licensing of services**

Governments are responsible for ensuring that prosthetics and orthotics services are provided only by qualified providers. This is usually effected by introducing a licensing or registration system and establishing minimum requirements, including qualification of personnel; adherence to national standards, rules and regulations; accountability and service unit infrastructure. Service providers applying for a licence or registration should declare any conflict of interests, for example with regard to upholding free competition, freedom of choice and user rights (see 2G and 4C).
Service providers who meet all the minimum requirements should be registered and given permission to practise. All licensed services must undertake audits and are expected to report statistics to the government or a designated office (see 1O). Service providers’ licences should be renewable after a certain period.

Licensing can be delegated to an independent State regulator but is usually financed by the government.

**Accreditation of prosthetics and orthotics professionals**

To ensure the quality of prosthetics and orthotics services and the safety of users, only professionals who meet national competence standards should be allowed to practise. Regulation of prosthetists and orthotists should be organized by the government (see 3J), including mechanisms for withdrawing the accreditation of professionals who make serious errors in clinical work or are involved in fraudulent activities, putting the safety of users at risk. The government may delegate accreditation to an independent State regulator.

**1C Monitoring**

Governments must monitor prosthetics and orthotics services to ensure that they develop towards the goals set in national policies and plans. Appropriate tools and procedures, measurable goals and benchmarks and performance indicators should be established to evaluate outcomes. Monitoring should include data collected from service providers (see 1O), which indicate the development of services and whether they meet the needs in terms of both quantity and quality. Monitoring should also include direct, regular auditing of service providers to verify their adherence to the standards, rules and regulations of the guiding framework as well as occasional evaluations of quality and also general assistance to providers in identifying and resolving problems.

Monitoring can be done directly by the government or be delegated to an independent office or authority, a national prosthetics and orthotics committee or an entity that coordinates and monitors the broader fields of health, rehabilitation and assistive technology. Evaluations and audits should be performed by a multidisciplinary team of experts external to the services being examined.

**1D International support**

In many low- and middle-income countries, the support of specialized international organizations is critical for setting up and improving prosthetics and orthotics services. Frequently, this occurs as a direct response to a disaster (see 4J). Organizations may contribute financial and technical support for service delivery, professional training, national policy development and planning and the development of tools and work processes; they may also directly supply components, materials and equipment. International support contributes
to raising awareness about the rights of people with disabilities and the need for and benefits of prosthetics and orthotics services.

The support of international organizations and agencies is usually limited in time and resources. Hence, long-term strategies and implementation plans for prosthetics and orthotics should be drawn up. Rather than considering international support as an isolated intervention to maximize immediate service outputs, the interventions should be integrated into national systems for long-term results. The victims of natural disasters or conflict are best assisted by strengthening existing service systems, ensuring that they function well in the long term and are available to all.

With national partners, international organizations may assist in developing effective, cost-effective models of service delivery at primary, secondary and tertiary levels that are adapted to the country. International organizations can also help in building local resources by supporting the establishment of national or regional centres of excellence staffed by well-trained local experts, which can provide support to other service providers when international support has ended. This approach has proven effective in many regional training centres and is important for the development of prosthetics and orthotics services.

### Costs

The costs of prosthetics and orthotics service provision are not only those for human resource, components and materials. To ensure provision of good-quality prosthetics and orthotics services, five main types of cost should be taken into account and covered. Each is discussed in more detail below.

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Notes</th>
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<td>service establishment</td>
<td>= investment cost</td>
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<td>training human resources</td>
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<td>service users</td>
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<td>national monitoring</td>
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Stakeholders involved in planning, establishing, running and funding prosthetics and orthotics services should comprehensively and coherently analyse these costs to understand the financial implications. Each category may require a different type or combination of funding.

#### Service establishment

Establishment of service units and systems requires capital investment in infrastructure and hardware, such as buildings, tools and machines. These are essentially one-off investments, but normal wear and tear will require financial provisions for maintenance, repair and replacement of items. These expenses are usually included in the costs of the service provider (see below).
The establishment of a service is usually financed by the service provider, such as the government, nongovernmental organizations (NGOs) or private investors. If a service is established privately, it may be financed by a loan, and the interest and reimbursements are included in the costs of the service provider.

**Training human resource**

Prosthetics and orthotics services require well-trained, qualified professionals. Substantial, continuous financial investment is needed to ensure sufficient numbers of prosthetics and orthotics personnel and to offer continuing professional development (CPD). With some exceptions, such training is done in institutions that do not provide regular services, and the funding sources are usually different from those for service providers. Supervised clinical placement is usually assured by prosthetics and orthotics services linked to an educational institution.

Prosthetists and orthotists and other personnel required in these services are usually trained in public or private institutions. Training is often paid by the students, but frequently with some type of subsidy from the government or a donor, such as a stipend. Governments should take responsibility for training and may provide funding if needed.

The costs of training prosthetics and orthotics personnel include those for:
- space, including lecture rooms and sections for practical training;
- tools, machines and other equipment;
- training materials;
- personnel (lecturers and clinical supervisors); and
- users in practical training (allowances).

Countries that do not have prosthetics and orthotics schools but rely on training institutions abroad have a different set of costs for each individual trained, including for education, study materials, travel, accommodation and allowances. These costs are sometimes covered by scholarships from an employer, government, civil society institution or donor.

**Service providers**

The costs of service providers are the regular expenses paid to deliver services, which may include:
- material costs, including taxes and charges related to procurement, such as value added tax (VAT), port charges, clearance and freight costs, importer’s margins and wholesaler margins;
- personnel costs;
- other running costs, including for telephone, Internet, electricity, water, fuel, cleaning, rent and insurance;
• maintenance of building, equipment, etc;
• depreciation (provisions for the replacement of worn-out equipment, vehicles, etc.);
• central, regional and local government taxes;
• interest payments and reimbursement of loans (if applicable); and
• any external service provided by therapists, doctors and other health and rehabilitation professionals.

In private services, the provider usually sets the prices in order to generate a net profit. This should be taken into account in calculating costs (see Box 2).

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**Box 2. Calculation of costs and price of prosthetics and orthotics services**

All service providers – public, private, NGO, philanthropic (see 4E) – should know the exact cost of service delivery and that of each type of treatment offered. Costs and prices can be calculated with a tool that can also be used to contain costs by identifying areas in which costs can be reduced and cost–effectiveness improved. The tools include that of ISPO (7). Calculations should take into account all service-related costs and make provisions for e.g. follow-up, maintenance and repairs.

For public services, salaries and infrastructure costs should also be included in the calculation, even if these items are covered by separate budgets. If these costs are not included, private service providers will not be able to compete on an equal basis, as their prices cover all their expenses.

Stakeholders can estimate the cost (or package price) of a complete treatment of a specified type for one person. This can be based on the prices calculated by service providers but is often higher. In low-income settings, for example, some of the costs of users might have to be covered in order to ensure that all people who need services can access them (see Expenses of service users below and 1M).

In the same way that the price of one vaccination has been calculated for immunization campaigns, a package price for prosthetics or orthotics treatment can illustrate the amount required to access the services. This figure is important for raising awareness at policy levels, lobbying for funds and selling the services. Calculations should preferably be made for each diagnosis, so that the cost for the entire population can be made on the basis of data on the prevalence of each disability.

Data on costs are also of interest to the international prosthetics and orthotics community, for making international comparisons and identifying models of cost–effective service delivery. The support of international bodies might be required in developing and standardizing comprehensive methods for costing.

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**Expenses of service users**

The expenses that are incurred personally by users when accessing a service unit and the loss of earnings should be considered in addition to service-related costs in order to derive the global cost of service delivery. The expenses may include:

• cost of travel to and from the service unit (sometimes requiring special transport);
• cost of accommodation at the service unit location;
• increased cost of meals during treatment;
• loss of earnings while away from work;
• cost of inability to perform normal activities in the community or household chores;
• cost of an accompanying person or persons (such as parents of children); and
• child care expenses.

Note: Although service fees constitute a major expense for users, they should not be considered a cost in this context but rather income for the service. (User fees are discussed in 1K.)

The expenses of users may be higher than the actual cost of service delivery and frequently constitute just as important a challenge to making services available, in particular in poorer settings. To facilitate access, user costs might have to be subsidized for the people at greatest risk for exclusion (see 1M).

National monitoring
Monitoring is the least expensive of the five main cost categories if a well-planned service system is in place. Prosthetics and orthotics services should be monitored to ensure that they are meeting the needs of the population and are adhering to established standards, rules and regulations. National monitoring is usually financed by public funding, although the tasks may be delegated to a nongovernmental agency.

Monitoring costs may include those for:
• a dedicated office or unit for monitoring prosthetics and orthotics services and
• personnel to administer coordination and planning, enforcement of regulations, audits and evaluation of services and national and international contacts.

1F Economic benefits
Prosthetics and orthotics services generate direct and indirect economic benefits for the person, the family, the community, society and the country. The services therefore not only have a cost but are an investment that yields both social and economic returns. Apart from the moral imperative to make this investment (to ensure that rights are respected and equity and development are achieved), there is also a clear economic case for financing prosthetics and orthotics services.

In making a cost–benefit analysis and identifying the economic benefits of these services, it is important to recognize the high cost of not providing these services to people who would benefit from them. As a result of treatment, individuals require less assistance from their families and other caregivers, releasing financial and human resources. The cost of not providing services may also increase over time, as secondary health conditions may require more expensive interventions. Gradually, whole families may become at higher risk
for poverty and more dependent on social support. Aggregated over time, such costs can soon be higher than the actual cost of treatment. It is therefore important to both provide the services and ensure that they are provided in a timely manner; early interventions significantly reduce long-term costs (see 1H).

National stakeholders, in coordination with the international prosthetics and orthotics community and disabled people’s organizations, could conduct more detailed studies to calculate economic benefits at all levels (from the individual to national) and present policymakers and planners with the results.

Direct economic gains at individual, family and community levels
Prosthetics and orthotics services contribute to making individuals more mobile and thereby more independent, which, in turn, has economic benefits. Rehabilitation of a person can reduce the costs of care and assistance and, for example, free financial and human resources in the family and the community, save the cost of institutionalization and reduce spending on health interventions and hospital visits. Rehabilitation can also result in an income for individuals and their families (and thereby society), as people who receive prosthetics and orthotics treatment can return to work or attend school and higher education, thus increasing their chances of earning an income later; they can also contribute to family tasks and community work. These benefits may be tangible in poor populations. Thus, prosthetics and orthotics may help people to escape from extreme poverty and hunger.

Direct economic gains at society and national levels
Benefits at individual, family and community levels will have an accumulated financial impact. Furthermore, the government will be able to make savings on social welfare, such as unemployment benefits and disability allowances. Hospital expenses will be reduced, as prosthetics and orthotics treatment may speed recovery and reduce or shorten hospital admissions. National health expenditure is decreased, as people with impairments or functional limitations become more active and healthier and require less health care. In addition, people who have undergone treatment and have returned to work will increase their financial contribution to society by paying income tax and generally increasing their spending. Thus, investments in prosthetics and orthotics services, and thereby in human capacity, can contribute to national economic growth.

Indirect economic gains at national level
Prosthetics and orthotics services also benefit the national economy indirectly. For example, service providers, like other employers, contribute to job creation and thereby reduce unemployment. Staff members, in turn, pay income tax on their salaries, and most services, particularly when provided privately, are taxable. Some countries also have large prosthetic and orthotic component industries, which may sell their products on the international market and generate considerable taxable income and profits.
1G Ensuring cost–effectiveness

Cost–effectiveness in prosthetics and orthotics services is a measure of responsible use of the available funds. Services that are cost–effective are more affordable and more widely available to more users. Efficiency is, therefore, necessary for equity in service delivery.

Measures to ensure cost–effectiveness

Ensuring the cost–effectiveness and growth of services should be part of the regular work of service providers and of stakeholders who monitor prosthetics and orthotics services. Several sectors should be analysed to determine where costs can be reduced and efficiency improved, without compromising quality.

At the service level, providers can investigate ways of reducing costs, by:

- setting realistic treatment goals and making appropriate choices of technologies;
- introducing alternative, cost–effective processes, components and materials (after appropriate cost–effectiveness analyses);
- ensuring the durability of prostheses and orthoses to reduce the frequency of repairs and renewals;
- providing maintenance and repair services to maximize the lifespan of prostheses and orthoses (see 4I);
- reducing waste;
- making sure that personnel at all levels and in all functions are well trained and skilled for the tasks they perform;
- appropriately balancing the ratio of non-clinical personnel per prosthetics and orthotics clinician (see 3H);
- increasing the specialization of staff members, so that they can gain more experience and skills in their field (see 3G); and
- task-shifting, so that primary health care (PHC) workers, therapists, social and community workers and community-based rehabilitation (CBR) workers provide a specific, well-defined range of prosthetics and orthotics services (see 4G).

A tool for calculating costs can help to identify areas in which costs can be reduced and cost–effectiveness improved (see Box 2).

Decentralization may increase the overall cost–effectiveness of prosthetics and orthotics services, including the expenses incurred by users (see 4H, Box 17).

Governments can also significantly reduce the costs of service delivery and make prostheses and orthoses more affordable, by:

- reducing or waiving import taxes on components, materials, tools, machines and other equipment used exclusively in prosthetics and orthotics services; and
- reducing or waiving value added tax on these services and products.
Tax regulations for prosthetics and orthotics services should be the same as for any other field of assistive technology.

The inclusion of some elements of these services into PHC can save costs due to early detection of needs, early treatment (see 1H) and the prevention of secondary impairments (see 1I).

1H Benefits of early detection and treatment of impairments

Avoidable impairments must be identified and treated as early as possible. In most cases, this can be done in PHC programmes, provided the staff have adequate training. Early interventions not only limit suffering and hardship but are also more economical, reducing the need for care and consequently the cost for families, caregivers and communities. When applied early, many prosthetics and orthotics treatments can correct and minimize deformities, which, if left untreated, would require gradually more complicated interventions and therefore more resources (see Box 3). The earlier treatment can be started, the sooner the economic benefits will be seen (see 1F) and the greater the accumulated economic gains.

Box 3. Benefits of early treatment of clubfoot

Some 150,000–200,000 infants are born with clubfoot each year globally (8). If these deformed feet are identified and treated promptly, the majority can be relatively easily corrected during the first few months after birth by a combination of manipulation, serial plaster casts, minor surgery and a brace. The cost of such treatment is low and represents only a fraction of lifelong disability benefits. If the deformity is not dealt with at an early stage, it will worsen, limiting mobility and access to education and employment. Eventually, it may lead to discrimination and exclusion from society. While clubfoot can still be corrected at a late stage, surgery and orthotic fitting are major, costly interventions, and the function of the foot will still be limited, even if the aesthetics are improved. Clearly, the cost of not intervening at an early stage is very high.

1I Prevention of avoidable impairments

Prosthetics and orthotics services are important in the prevention of secondary impairments, through a combination of information, advice and orthotic treatment. Examples include the care of people with diabetes, who are at risk for amputation as a result of foot ulcers (9) (see Box 4), management of idiopathic scoliosis during growth (10) and the prevention of contractures in burns.

Preventing secondary impairments has direct benefits for the person and the health system. For the person, the absence of functional limitations means a better quality of life, as it is easier to participate in home, work and family life, and it is less likely that complications will develop. For the health system, there is less pressure on the resources needed for severe health conditions.
Box 4. Prevention of amputation in people with diabetes

People with diabetes may lose sensation in the feet (neuropathy). This, with a poor blood supply due to restricted blood vessels, increases the risk for damage to the feet and for foot ulcers, which can lead to infections, amputation or even death.

Diabetes is a sizeable health challenge, as 8.5% of the world’s population have the disease (11), and people with diabetes have a 12–15% chance of a foot ulcer in their lifetime (9). Strategies to reduce the risk for foot ulcers include preventive advice, awareness campaigns and identification of cases of diabetes in the community and primary care settings. Foot ulceration can be prevented by screening people with diabetes to identify those at risk and showing them proper foot care (12). For those with foot ulcers, compliance with orthotic treatment and the use of protective footwear can help to prevent major limb amputation (13).

Prosthetics and orthotics services have a role to play in the prevention and treatment of diabetic foot ulcers, preferably in a multidisciplinary foot clinic. The principal treatment is mechanical offloading with total contact plaster casts (14), therapeutic footwear (13) or another orthosis to protect and stabilize the foot and ankle, depending on the severity of the condition. If limb amputation is required as a lifesaving measure, these services can offer a prosthesis after amputation. For people who undergo unilateral amputation because of diabetes, orthoses and special footwear can help prevent the development of ulcers and later amputation on the sound side.

Universal health coverage

The concept

Universal health coverage is defined by WHO 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.” (15).

In this concept, user fees (out-of-pocket payments) are reduced by the use of funds pooled from various sources, usually including general tax revenues and mandatory earmarked contributions for health and social insurances (payroll taxes). The services thereby become affordable for vulnerable and poor populations, who are at risk of sliding into poverty when they have to pay for health services from their own pockets. Universal health coverage is therefore a critical component of sustainable development and poverty reduction and a key element of all efforts to reduce social inequality.

The concept can be illustrated as a three-dimensional box (Fig. 1), which represents the funds required to provide all health services free of charge to the whole population. Once a certain level of pooled funding has been secured (the blue volume), policy-makers can decide how to allocate the money: which sector of the population to insure (dimension 1; population coverage), which services to include (dimension 2; service coverage) and how much to charge people for access to those services (dimension 3; financial coverage). To provide more coverage, either funding or efficiency must be increased. It may not be possible or even desirable to pool enough funds to fill the larger box; the challenge is allocating the available funds so that the widest range of services can be provided to the most individuals in the most equitable way.
WHO generally recommends that countries establish large risk pools by maximizing mandatory prepayment and use general government revenue to cover people who cannot afford to contribute. This good practice is based on sound health financing principles.

**Prosthetics and orthotics services**
Prosthetics and orthotics services constitute an important part of health services and must therefore be taken into account in moving towards universal health coverage, especially when the addition of other services is being considered. Like other health services, prosthetics and orthotics services must be financially accessible for all potential users and should therefore be included in the benefits package (dimension 2 in Fig. 1).

Certain prosthetics and orthotics treatments may be higher priorities for subsidies than others. WHO’s “priority assistive products list” (see 2D) serves as a guide for governments, indicating which products are essential. Where financial resources are limited, governments – represented by their ministries for health, social welfare and finance and in collaboration with other stakeholders – will need to determine which products (and their technical features, see 2B) should be subsidized and to what extent. Therefore, a full economic costing should be conducted for each product in order to derive the complete cost of delivering the services (see 1E).
Financing

Health financing is much more than about raising money for health. It is also a matter of “who is asked to pay”, “when they pay” and “how the money is spent”. The way that money is raised to cover health costs is usually referred to as “revenue collection” (16).

Experience from the financing of medicines has shown that the critical factors for success are political commitment, administrative capacity, clear implementation strategies, financial sustainability, rational selection of products, affordable prices, a reliable supply system, and low taxes. Inequalities in access to treatments, particularly in resource-poor countries, are mainly due to inadequate public spending, a lack of adequate health insurance coverage, poor availability of essential supplies, poor affordability, and high household out-of-pocket expenditure (17). It may be assumed that the same applies to prosthetics and orthotics services.

Government commitment is critical to establishing adequate, sustained financing for prosthetics and orthotics services. With stakeholders, governments can devise financing models suitable for the country’s institutional, economic and social context, while encouraging diversity and choice with regard to technologies, components and materials.

Funding resources for prosthetics and orthotics services usually come from general and specific taxation, public health and social insurance, private insurance and medical savings accounts, user fees (out-of-pocket payments), donations or a range of less common but still important sources. Funding is often a mix of these sources, the distribution of which may differ among countries and change within countries over time. All funding sources must be explored, in particular in poorer settings, as a single source may not cover all service needs. Funding mechanisms must always be based on transparency and accountability, with clearly defined financial procedures and rules, for example in issuing purchase requisitions.

In order to ensure a sustainable financial model, countries are encouraged to move towards predominant reliance on compulsory funding sources, such as general tax revenues, earmarked payroll taxes or a combination of both, as typically voluntary mechanisms often suffer from major shortcomings (18). This strategy contributes to sustainability and including prosthetics and orthotics services in universal health coverage.

General and specific taxes

In some countries, prosthetics and orthotics services are funded with tax money raised by national or provincial governments. The taxes may be general income or specific taxes, such as value added or excise taxes. Tax funds may be channelled through a ministry directly to prosthetics and orthotics services, or as direct payments or vouchers to the users, who can obtain the services required for their individual needs.

Governments may use tax funds to subcontract services to private enterprises or NGOs. Subcontracting should be done by recurrent, open tendering, and services should be
commissioned to ensure quality and not only advantageous cost. Various cost-sharing arrangements are possible. For example, government funds might be used to cover the salaries of the personnel of an NGO, while the NGO pays for the components and materials and delivers the services.

**Public health and social insurance**
In many countries, prosthetics and orthotics services are funded through public health and social insurance systems. In such systems, the country’s entire population is entitled to health care coverage, usually in a cost-sharing arrangement, with the user paying a service fee. Insurance is usually financed by compulsory prepayments (social insurance premiums or other government charges), which are pooled to spread the risks throughout the population (see 1J). The health and social insurance systems of many countries do not, however, cover prosthetics and orthotics treatment, and national stakeholders should advocate for the inclusion of such benefits.

The extra cost of including prosthetics and orthotics services as a component of national health and social insurance is expected to be comparatively low. The direct results of doing so may, however, be significant, as coverage may dramatically increase access to services, thereby contributing to universal health coverage. The costs should be calculated (see 1E) and compared with the economic benefits for individuals and society (see 1F).

**Private health insurance and medical savings accounts**
Prosthetics and orthotics services are sometimes funded by private health and accident insurance, workers’ insurance or similar, which is often co-financed by individuals and their employers. Such insurance may be compulsory and mandated by law.

In this option, health care is often provided based on the individual’s ability to pay rather than evaluation of health needs, negatively affecting the unhealthy. The concept of a medical savings account (MSA) is a mechanism that allows people to save money monthly to spend in the future on health care. The philosophy behind this concept is that if people are forced to save their own money to cover costs, they may be more responsible when it comes to consumption or expenditure (17). In some countries, MSA funds are used to cover the costs of prostheses and orthoses.

Many countries have private health insurance systems in parallel to the public health insurance systems. Private health insurance systems usually offer better coverage for people who can afford it. In countries where private insurance is the sole system, poor people risk exclusion from the services unless insurance premiums are subsidized by the government (19). Furthermore, prosthetics and orthotics services are often not included in the benefits package of many private insurance companies and inclusion may therefore have to be promoted.

**User fees**
In some circumstances, prosthetics and orthotics services are paid in part or in full by the service user. Payment in part may be referred to as household out-of-pocket payments and
is often proportional to the amount of care consumed (17). Overly high service fees have a direct negative impact on access and the use of services, and many people risk exclusion (20) (see 1L). Large user fees that lead to catastrophically high expenditure push people, families or households into debt and poverty cycles. When user fees are the main source of funding for prosthetics and orthotics services, service providers must make various levels of technology available, including affordable, low-cost alternatives for people who cannot pay for an expensive product range.

**Donations**

In some situations, prosthetics and orthotics services are financed by donations, for example from charity organizations and NGOs, which may sometimes also provide services. The risk associated with such an approach is that not enough attention is paid to the outcome of the service or to sustainability. To ensure quality and user satisfaction, charity services should be evaluated in the same way as other services.

When services are provided with donated funds, they are often free of charge for the service user. This can lead to abuse of the system and also seriously undermine the efforts of providers that do not rely on donors to create sustainable services. Application of a small service fee can have a positive effect (see 1L). Sometimes, particularly in poorer settings, donations may include components, materials or second-hand prostheses and orthoses. If such in-kind contributions are not coordinated, they may be of little help to the service provider (see discussion on donations and reuse of components in 2F).

**Other funding sources**

Funding for prosthetics and orthotics services may also come from other, complementary sources, such as trust funds, credit unions, lotteries, private institutions, multinational companies, corporate social responsibility initiatives and various types of foundation. In some instances, local communities may be able to contribute funding to individual service users, and, in some countries, earmarked funding from a “sin tax” (e.g. a tax on tobacco or alcohol) may be used.

Service providers can also use a socially oriented system, in which the profits made from users who can pay the full cost of treatment or who can afford more advanced products are used to subsidize services for those who have less financial means (cross-subsidized funding). This is usually the case of private social enterprise organizations, which reinvest profits into services in order to maximize social well-being.

Another possibility is community health financing, a system comprising consumer payments such as user fees, pre-payments etc., for community delivered health care, with proceeds retained and managed within the local health sector. This method often serves as a means for communities to be active, rather than passive participants in their health system and may aid in the provision of prostheses or orthoses (17).
Considerations in applying service fees

In some prosthetics and orthotics systems, services are provided free of charge. Although this may appear to be ideal, in particular in settings with limited financial resources, the policy must be evaluated carefully.

The benefits of asking for payment for services include:

• making users more aware of the value of the treatments and more appreciative of the services;
• allowing users to bargain for better quality;
• encouraging users to maintain the products they receive;
• reducing abuse of services; and
• generating an income that, although perhaps small, helps to sustain the services.

User fees can, however, pose a significant barrier to large sections of the population and jeopardize the attainment of universal health coverage (see 1J). The right level of fees must therefore be set. In poor settings, the fee might have to be very low or merely symbolic for many users. Even a token payment can give rise to most of the positive effects listed above. The appropriate level of fee might have to be decided case by case by evaluating the socioeconomic status of individual users.

Caution is required when services are provided from mobile units or in outreach activities, where it might be particularly difficult to ask for payment, as this might deter people from using the services.

More evidence is required on the impact of user fees on the use and sustainability of services in different economic contexts and for different types of service delivery. Research should be conducted by national and international stakeholders in this area.

Facilitating access of users

Travel to a service location and staying throughout treatment sometimes incurs considerable indirect costs for users (see Expenses of service users in 1E), particularly those who have to travel a long distance or require assistance and regular appointments. Many users may also have spent part or all of their savings on surgery and other medical treatment.

In many countries, even if the treatment is free of charge, user expenses may deter people from seeking the services. In order to minimize travel costs and time spent away from home, the services should be decentralized as much as possible by their inclusion in health services (see 4F and 4G) and other means (see 4H). If access is still difficult, the service provider, government or other stakeholders (including the local community and civil society) might consider subsidizing travel-related costs for people at greatest risk of not accessing the services.
services. Such support should preferably be temporary, so as not to create dependence. If users are satisfied with the services and experience direct benefits (including financial ones), they might be readier to find ways to cover travel-related costs the next time they require the services.

Assessing the need

Accurate data on the needs and unmet needs for prosthetics and orthotics are indispensable for planning and developing services. Information is required, for example, for workforce planning (see 3H) and for assessing the number of service units to be established in a country or region (see 4G, Box 15). The need for services can be assessed by using the general WHO estimate of 0.5% (21), from data on the prevalence of disability, by using data from national censuses, by analysing service utilization or by conducting a dedicated survey (all discussed below). Some of these methods also indicate the level of unmet need. As a complement to these approaches, the demand for services (the number of people actively requesting assistance) should be considered; however, it is important not to equate demand with need, as many people who could benefit from these services are unaware of them (see Box 5).

Box 5. Need versus demand

The terms “need” and “demand” should be distinguished. “Need” is the actual number of people who could benefit from prosthetics and orthotics services, while “demand” is the number of people who actively request assistance. In many countries, the demand for services is very limited; frequently, there are no queues outside service units, and waiting lists – if they exist – are often short. This may give the false impression to decision-makers and other stakeholders that the need for services has been satisfied, even though the unmet needs may be overwhelming. People who need services do not demand them because, for example, they may:

- not be aware the services exist (even health care professionals who could refer them to prosthetics and orthotics services may be unaware of their existence);
- think the services could not help them;
- think they are not entitled to the services;
- find the services inaccessible or too far from their community;
- have had experience of poor service delivery in the past and do not want to try again; or
- be unable to afford the services.

Consequently, governments and other stakeholders cannot rely only on reports of demand. Clear evidence of need is required to make informed decisions. Services should not be provided only to those who are vocal or live in large cities.

People’s demand for services is of value for expanding services and making them more accessible. In countries where many individuals demand these services – by requesting assistance at service units, hospitals, public offices, etc. – governments are usually more aware of the need for services and are more likely to take concrete steps to develop them.

Data on national needs and unmet needs for prosthetics and orthotics are often difficult to obtain, as government data collection methods are not yet sensitive enough to identify people with all kinds of functional limitation. By building on and improving the methods,
the international prosthetics and orthotics community could support the development of a standard needs assessment tool, based on the WHO International Classification of Functioning, Disability and Health and taking into account existing and emerging data collection templates (22).

In determining the need for prosthetics and orthotics service, replacements should also be taken into consideration. The need of many users is lifelong, and their devices must be replaced regularly as they wear out or no longer fit. The average lifespan of different types of prostheses and orthoses can be estimated from service data, and this information can contribute to sector planning.

Calculating need on the basis of the WHO general estimate
WHO estimates that one in every 200 people (or 0.5%) need a prosthesis or orthosis (21). This is an approximate figure that does not take into account regional differences or factors that result in higher rates in certain populations, such as war, disabling diseases and road traffic injuries. Nor does it account for factors that reduce need, such as prevention programmes and good medical care. It obviously does not indicate the types and numbers of different prosthetics and orthotics treatments needed or the distribution by gender and age. It does provide a basis for a first calculation of need and thus of the service system required to assist the population concerned. The estimate can serve as a starting point for general planning, to be complemented with more exact assessments later.

Estimating need from data on the prevalence of health conditions
Data on the prevalence of disability, to the degree that they are available, can be used as a complement to the 0.5% estimate to determine the proportions of different types of prosthetics and orthotics treatments needed. Epidemiological data on the most common diseases and diagnoses relevant to prosthetics and orthotics (including diabetes, spinal cord injury, vascular diseases, cerebral palsy, polio and amputations) can give a general indication of the numbers and types of treatments and devices needed in a defined geographical area, which can be extrapolated to national needs. Information for this purpose may be obtained from the health sector, individual hospitals, national registers (see Box 6, below) or national records on trauma-related injuries. Similar information can be obtained from CBR programmes; disabled people’s and user organizations may also be able to provide data on the impairments commonly seen in their groups.

Estimating need from national census data
In most countries, national population censuses are carried out by the government every 10 years. In some countries, censuses include questions on disability, usually those endorsed by the Washington Group on Disability Statistics (23). These data are, however, often inaccurate, as they are obtained from heads of households for all family members and not on first-hand information. Such statistics, which are usually not specific to prosthetics and orthotics, should preferably be complemented with data from other sources.
Estimating minimum needs from service utilization
The utilization of prosthetics and orthotics services is often strongly correlated to the proximity of those services to potential users. Use is likely to be highest by populations close to a service unit, in particular if the services are financially accessible, well known and have a good reputation, such that the need for prosthetics and orthotics services may be almost met. Data on use of the services in the area will indicate the proportion of the population that was assisted. Application of this value to other geographical areas can give a preliminary estimate of the minimum need that can be expected in other regions and in the country. The calculation can be refined by considering factors that are likely to influence need in different geographical areas.

Determining need in a dedicated survey
Sample surveys can be conducted to obtain more precise estimates of need and unmet needs for prosthetics and orthotics in a country or region, thereby also indicating inequity. Surveys are, however, technically difficult and may also raise expectations in the population that may not be immediately fulfilled. Unless the purpose of the survey is properly explained to the people interviewed, it may create frustration and mistrust among individuals who need assistance. As surveys are expensive, it may be more effective to conduct a small sample survey in a country where the need is overwhelming and extrapolate the results. The savings made by not conducting a large data collection exercise can be used to make services available to more people in need. By keeping accurate records, it will be possible gradually to understand the extent of the need for services (see previous section).

When a survey is conducted, it should obtain information on all types of prosthetics and orthotics needs and not any particular need (such as that of people with conflict-related impairments). When data are sought for one group, a survey usually offers an opportunity to collect information on other groups too. Attention should be given to ensuring that girls and women are not neglected.

The personnel conducting screening, assessments and interviewing should have sufficient training to be able to identify needs. Otherwise the recorded figures may be too low, resulting in an incorrect assessment of the resources and interventions required to provide appropriate assistance. As surveys are usually one-off exercises, it may take a long time before flawed values are corrected.

Collection of data
Data to assess the need for prosthetics and orthotics must be collected, analysed, compiled and used at service and at national and global levels.

Data collection at service level
In order to monitor access to service and successes and challenges, every service provider should collect basic data on the number of people treated and the type of services they
received. Consistent recording, monitoring and analysis of data not only provide a picture of the effectiveness of services but also give an indication of the need for services in the service unit’s catchment area (see 1N). Service providers should also collect information on who the users are and how the unit reached different groups, followed up users and ensured the quality of treatment (Table 1). The purpose of collecting data must be fully understood by the service providers. Only data that will be used should be collected.

<table>
<thead>
<tr>
<th>Data</th>
<th>Purpose of data (examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of people treated and types of treatment provided</td>
<td>To understand the magnitude and breadth of services for planning procurement of components and materials</td>
</tr>
<tr>
<td>Socioeconomic status of users</td>
<td>To ensure that services also reach the most marginalized groups</td>
</tr>
<tr>
<td>Proportions of women and children among those assisted</td>
<td>To determine whether additional measures are needed to target these groups (such as increasing the number of female personnel)</td>
</tr>
<tr>
<td>Age groups</td>
<td>To ensure that children, young people and the elderly are included to the same extent as other age groups</td>
</tr>
<tr>
<td>Geographical origin of users</td>
<td>To determine the success of services in reaching remote parts of the intended catchment area</td>
</tr>
<tr>
<td>User experience (from questionnaires or focus group discussions)</td>
<td>To determine the quality, affordability and accessibility of services and factors that prevent use and compliance</td>
</tr>
<tr>
<td>Impact of the services on quality of life, participation and inclusion</td>
<td>To determine the usefulness of delivered prostheses and orthoses and their contribution to enabling the user to work, go to school, participate in social activities, etc. (see 1P)</td>
</tr>
<tr>
<td>Waiting and delivery times</td>
<td>To indicate whether the services are user-friendly</td>
</tr>
<tr>
<td>Referrals (in and out): by and to whom and how</td>
<td>To determine the success of networking, awareness-raising and mechanisms for referral</td>
</tr>
<tr>
<td>Follow-up services: how many and who</td>
<td>To verify that appropriate follow-up services are provided to all users, irrespective of where they live or where they are treated, at a central service unit or through decentralized services</td>
</tr>
<tr>
<td>Repair services: how often required, type, reason</td>
<td>To determine the technical quality of delivered products</td>
</tr>
<tr>
<td>Frequency of replacement of prostheses and orthoses</td>
<td>To determine the lifespan of products and therefore annual production needs</td>
</tr>
<tr>
<td>Abandonment of prostheses and orthoses, including rates and reasons</td>
<td>To determine quality issues and areas to be improved</td>
</tr>
<tr>
<td>Main causes of disability</td>
<td>To determine the main types of treatment needed; monitoring over time will indicate trends in disability for setting directions for services and predicting training needs</td>
</tr>
</tbody>
</table>

The collection and analysis of data can be facilitated by ensuring that they are an integral part of the service unit’s day-to-day work. Full use should be made of service user management systems so that relevant statistics can be extracted and used (preferably in graphic form
to illustrate trends over time). The international prosthetics and orthotics community could facilitate data collection and analysis by developing standard, user-friendly tools and methods that can be used in services and at national and international levels (see below). The confidentiality and privacy of users must be respected by anonymizing data collected for statistical purposes.

Data collection and compilation at national level
National stakeholders require data for monitoring service delivery and for more detailed planning. Many of the data on services can be compiled to produce national statistics, which facilitate the analysis of time trends and identification of areas in which action is required to improve service delivery. Information about service delivery should also be prepared for decision-makers and others to raise awareness about the achievements, challenges and general role of prosthetics and orthotics services (see 1Q). Data are also useful for insurance companies, which might be willing to invest in data collection.

Standardized tools and methods will facilitate data collection and analysis (see previous section). As at service level, only data that will be used should be collected. Compilation of data at national level can be facilitated by direct entry of data into a national database, such as a register (see Box 6). Such a database could be linked to or integrated into the national health management information system.

Box 6. Use of national registers

A national register is essentially a database to which service providers submit results to provide a comprehensive view of prosthetics and orthotics services. Regional or provincial registers could supply data to the national register.

In countries in which there is the risk that users will request subsidized (or even free) services from several providers, a national register of users and the services provided could facilitate coordination among units to prevent overlap of supply. This can prevent fraudulent use of services and ensure that limited resources benefit the maximum number of users.

A national register may be more comprehensive and be used to collect data for planning, monitoring, evaluating and awareness-raising. All licensed service providers should be expected to submit a defined set of data to the responsible organization, ministry or office at national level. Decisions should be made on how the data are to be collected, maintained and retained.

An expanded national register could also include data on processes beyond prosthetics and orthotics, including cross-sectoral data on interventions throughout the continuum of care, such as from amputation to prosthetic fitting and complete rehabilitation, as in the Swedish register (25). Such a register can allow objective evaluation of the quality of the entire rehabilitation process, providing valid information and recommendations on appropriate treatments. Contribution of data to the national register might not have to be compulsory, as service providers would usually consider it an advantage, as the outcome will benefit the whole sector and, ultimately, the user.

Use of data at global level
Data produced at service and national levels is also of interest at global level and can be collected and compiled by international stakeholders in prosthetics and orthotics. Global statistics indicate the challenges faced by these services in different parts of the world
and how they can be met, including examples of successful service delivery systems. Standardization of tools and methods with ISO terminology for prosthetics and orthotics (see 4P, Box 26) would facilitate such exchanges.

**1P Data on impact**

It is important to establish the direct impact of prosthetics and orthotics services on individuals, i.e. the degree to which the services contributed to improving the quality of life, social inclusion and economic status of beneficiaries. The availability of standardized evaluation criteria would facilitate international comparisons.

As most users return at some point to the service unit for repairs or renewal of their devices, they can be asked about how useful the prosthesis or orthosis is, when it is used, how much it is used, whether it has enabled the user to work, go to school and participate in social activities and whether it has improved the user’s self-determination and confidence. Systematic data collection as part of service delivery is an economical way of assessing impact.

For a more detailed, scientifically more accurate assessment, an impact study may be conducted. This may be beyond the capacity of individual service providers, requiring a commitment from the government or stakeholders and earmarked funding. Verification of the impact of services is in the interest of all parties, to ensure that the investments generate good results. Impact studies usually involve visiting beneficiaries in their communities, first to make a baseline assessment and then to measure change. Studies can be facilitated by liaising with user groups and community services in health, social or education sectors.

**1Q Awareness-raising**

Prosthetics and orthotics are relatively unknown, even in the health sector, and the public may not understand what the services provide (see 1R). More disturbingly, the very people who could benefit from these services are often unaware of their existence and consequently may not demand them. This may give the false impression that there is little need for services (see 1N, Box 5). In many countries, therefore, awareness about the need for and benefits of the services must be raised, from the level of decision-making (policy development and national planning), to health and social professionals (who refer users) to districts and communities (where the people who need the services live).

Member States have an obligation to promote use of assistive devices and technologies (1). With national stakeholders, governments should make prosthetics and orthotics services known and develop awareness that these services are indispensable and merit investment. Strategies and tools for awareness-raising should be developed for this purpose as part of strategies in the broader field of disability.
Awareness-raising strategies should be based on rights-based arguments (with references to national laws, decrees and policies and international documents, such as the CRPD and the SDGs) and also on social and economic arguments of the costs and economic gains at individual, community and national levels (see 1E and 1F). In some cultures, disability is seen as a punishment, and people with disabilities are hidden and neglected (26). Such barriers should be removed to ensure access for all to prosthetics and orthotics services.

User groups have an important role in lobbying and awareness-raising for policies. Demands by users demonstrate the need for these services and are a complement to collected data. Their demands sensitize decision-makers to real experiences, so that they will be more inclined to take action.

At referral level, awareness-raising is best conducted during training of professionals in health and social sectors. Stakeholders in prosthetics and orthotics should work with relevant training institutions to ensure that prosthetics and orthotics are appropriately introduced in the curricula and the role of these services is made clear (see 3E). Awareness should also be raised by working with stakeholders in referral networks.

At grassroots level, awareness can be raised by liaison with programmes for similar missions that target similar groups, such as poverty reduction programmes, vaccination campaigns, civil society actions, disability-inclusive sports and recreation programmes (see Box 7) and CBR programmes. The availability of good-quality services will, in itself, directly raise awareness among potential users. When users learn that friendly, reliable services are available and can make a great difference to their lives, many will tell others. When services are affordable, easily accessible and of high quality, little awareness-raising will be needed. Every satisfied user is an ambassador for the prosthetics and orthotics sector.

International awareness-raising activities can support national and local initiatives by providing guidance and information resources that can be adapted nationally to improve the efficiency of local campaigns.

A core feature of awareness-raising is information campaigns. Before launching a campaign, the target groups should be identified (e.g. the general public, decision-makers, health professionals, social workers, potential users) and the content, mode and medium of dissemination decided. Information can be disseminated, for example, on television and radio, in newspapers, on the Internet and in social media, by civil society, faith-based and humanitarian organizations, at theatres, in schools and on posters and leaflets. Awareness-raising also includes having good role models, by increasing the visibility of users in everyday situations, such as in television series and sports events.
Sports and recreation are generally important for health and well-being and are often beneficial in rehabilitation. Such activities not only ensure that prosthetics and orthotics service users benefit from physical training but can also contribute to social inclusion. Many countries have dedicated sports programmes for people with disabilities – such as track and field, wheelchair basketball and water sports – some of which are governed by a national paralympic committee. Some athletes with disabilities are integrated into able-bodied sports organizations. Prosthetics and orthotics service units could liaise with disability-inclusive sports and recreation programmes and provide technical support to people with disabilities, at both professional and amateur levels. The provision and maintenance of prostheses and orthoses may be a precondition for the participation of people with disabilities. Such support clearly contributes to social inclusion and to raising awareness about the rights of people with disabilities and the role of prosthetics and orthotics services.
Strengthening the image

The challenge
In many countries, the prosthetics and orthotics profession is misunderstood as technical work that, although it might require certain manual skills, does not require much theoretical or clinical knowledge. As a consequence, it is often reduced to craft work or as noisy, dusty work preferably performed in the basement or backyard of a hospital, if at all in a hospital environment. In poorer settings, a prosthetics and orthotics service may resemble a repair workshop rather than anything related to clinical work and medical science. As long as this perception prevails, and even if the professionals are skilled and the results important, it will be difficult for decision-makers to understand that these services are worth investing in.

National stakeholders should change this perception and make it clear, particularly to policy- and decision-makers, that this is important work that requires years of training in a wide range of theoretical subjects. Like other health and rehabilitation professionals, such as physiotherapists, occupational therapists and podiatrists, prosthetists and orthotists usually receive training at university, with some continuing to masters and doctorate degrees. They work closely with doctors, share the same medical language and make an important contribution to the health sector. This is the image that should be promoted.

Strengthening the image
A number of measures can be taken to strengthen the image of prosthetists and orthotists among decision-makers, health professionals and rehabilitation professionals in particular. Many of these measures do not require a large financial investment, especially if they are considered at the planning stage. Generally, they consist of the way in which the services are presented and how they interact with other services.

Ensure that prosthetics and orthotics services are an integral part of the health system.
- When possible, prosthetics and orthotics units should be integrated into hospitals, with close, direct links to orthopaedics, surgery, rehabilitation, physiotherapy and occupational therapy departments. This will not only make the services more effective but will increase the perception that the profession is equal to other health professions.

Present positive outcomes of prosthetics and orthotics.
- Demonstrate concrete outcomes in functioning and participation, including socioeconomic gains, in users, their families, their communities and the whole country.

Promote national recognition.
- If it is not yet the case, work with national authorities and other stakeholders to recognize prosthetics and orthotics training, the profession, the services and the sector as such.
- Promote the establishment of national prosthetics and orthotics associations or societies.
**Ensure professionalism.**

- Make sure all prosthetics and orthotics personnel are well trained and use proven technologies and working methods based on the best available evidence.

**Consider the appearance of the services.**

- Make sure that all areas of the service unit have a professional look.
- Make sure that user areas are similar to those of modern hospitals, with a welcoming, comfortable environment. Waiting rooms and clinical areas should be well separated from the noisier, dusty activities of the workshop.
- Keep all areas, including assembly and machine rooms, clean, neat and tidy.
- Make sure all personnel are competent in addressing users.
- Make sure a user policy is in place and that services are truly user-oriented and gender-sensitive (see 4A).
- Promote the wearing of clinical uniforms and name badges by all personnel in contact with users.
- Always consider dress code when representing the services, in particular for personnel in direct contact with government agencies or offices.

**Carefully consider the choice of terminology.**

- Refer to prosthetics and orthotics units as “departments”, “clinics”, “laboratories” or “centres” and not as “workshops” or “limb-fitting centres”, as these terms perpetuate the view of prosthetics and orthotics as merely technical work. While “prosthetics and orthotics workshop” is a valid term, it should be used only when referring to the room or section of the service unit where prostheses and orthoses are fabricated.
- Use the terms “prostheses and orthoses” and “prosthetic and orthotic products”, and avoid the terms “calliper” and “appliance”, as these are outdated.
Area 2. Products

2A Appropriate technology

In prosthetics and orthotics, the principal definition of appropriate technology is that of ISPO:

Appropriate technology is a system providing fit and alignment which suits the needs of the individual and can be sustained by the country at the most economical price. Proper fit and alignment should be based on sound biomechanical principles (27).

On the basis of this definition, detailed criteria can be used to evaluate the appropriateness of technologies, components, materials and working methods locally. Appropriateness can be considered from three main perspectives: acceptability by users, economic feasibility and technical suitability. Criteria are proposed in Box 8; however, national prosthetics and orthotics stakeholders should draw up their own criteria to guide evaluation of the appropriateness of different technologies (28).

Cost–effectiveness in prosthetics and orthotics services is strongly determined by the choice of technology and, for that technology, the choice of components and materials. As components are available from a number of suppliers, with variations in models and prices, the market must be searched continuously to find the most cost–effective options, while carefully considering quality, durability and availability.

More than one technology may be appropriate, and several technologies of different levels of sophistication and price can be used in parallel. Any technology that is requested, paid for (by the individual, the system or a third party) and does not restrict access to services
can be viewed as appropriate. This includes expensive and highly sophisticated products for users who have the financial capacity or insurance coverage to pay for them (and service providers with the necessary technical capacity to supply them).

**Box 8. Criteria for determining the appropriateness of technology**

The following criteria may be used to determine the appropriateness of prosthetic and orthotic technologies, components, materials and working methods.

**User-related criteria:**
Products should:
- be comfortable, with a well-adapted interface between the body segment and the device;
- be functional;
- be easy to put on and remove;
- not endanger user safety;
- be durable;
- have the best possible cosmetic appearance (e.g. shape, finish, colour);
- be biocompatible (for example, not provoke allergic reactions);
- not be too heavy (in most cases, they should be light);
- be acceptable by and adaptable to the majority of users, i.e. they should:
  - generally suit the user’s needs;
  - be culturally appropriate, thus, should respect the culture and lifestyle of individuals, which may include such aspects as walking bare-foot, squatting and sitting cross-legged;
  - suit the climate (and, if necessary, be resistant to humid, wet conditions);
  - suit the local terrain; and
  - suit local working conditions.

**Economic criteria:**
- Products should be affordable by the system and/or the individual.
- Technologies should be cost-effective; they should be:
  - clinically effective;
  - allow for rationalization of production methods and swift fabrication;
  - not require many tools and machines or very advanced, expensive equipment;
  - require low service maintenance;
  - generate minimum waste; and
  - made of readily available components and materials (on the local market or imported).
- Technologies should promote sustainable development by enhancing local entrepreneurship and making use of local markets, such as locally produced components or materials.

**Technical criteria:**
- Technologies and working methods should be of proven, documented efficacy and safety.
- Technologies and working methods should adhere to international standards.
- Technologies should ensure biomechanically correct products that can be given proper alignment.
- Products should be durable and have a long lifespan.
- Products should be easily adjusted, maintained and repaired (as far as possible by the users themselves).
- Prosthetists and orthotists should have sufficient skill and knowledge to apply technologies and working methods; if this is not the case, training must be practically feasible and affordable.
- Working methods should not be hazardous to personnel.
- Materials should be easy to store.

The priority of these criteria may vary according to the setting, but all should be considered.


**2B Overview of product features**

The prostheses and orthoses available on the market have various design features. Thus, the same type of product may be made in different ways with more or less sophisticated components, materials and techniques. The main criterion for choosing a prosthesis, orthosis or component part is usually not its degree of sophistication but its general appropriateness to the needs of the user and the setting in which it is fabricated, fitted, used and financed (see 2A).

Regardless of the product used, the service is the same (see 4P), with essentially the same requirements for equipment, tools and trained personnel. The quality requirements should also be the same. At each level, products should be comfortable and functional. Ideally, service providers should be able to offer a full range of products, so that all kinds of need and preference of users can be met. In reality, government funds, insurance and other sources of funding are unlikely to cover all product types, and priorities should be set (see 1J and 2D).

Four design elements characterize prosthetic and orthotic products: geometric configuration (shape and alignment), materials, resistance to movement and powering of movement.

**Basic prosthetic and orthotic products** provide the essential functions and comfort for the user. They usually are made of a narrow range of materials, such as lightweight thermoplastic, steel and/or aluminium materials. The components may include single-axis joints and cushioned-heel feet for prostheses and sidebars for orthoses. Basic prosthetic and orthotic products are usually of relatively low cost. Such products are needed and appropriate for use in all countries. In poorer settings, use of basic products is usually a requirement for reaching large populations in need and serves as a step towards higher levels of product.

**Intermediate prosthetic and orthotic products** are made of a wider range of materials, such as thermoplastics, thermosetting (composite) materials, steel, aluminium and/or titanium. The components may include four-axis knee joints and articulated (single or multi-axis) feet for lower-limb prostheses and more advanced sidebars and polycentric joints for orthoses. Supplementary control of joint movement may be powered by the body and/or by more sophisticated geometric design, friction, pneumatic or hydraulic components. In prosthetics, for example, pneumatic or hydraulic cylinders are used to control the knee throughout the swing phase and to control its stability during the stance phase. While this may be the standard product in most high-income countries, both basic and advanced products can be used to ensure that services are provided in all settings and are adapted to the financial resources and needs of individual users.

**Advanced prosthetic and orthotic products** are made of at least the same range of materials and components as intermediate products but have additional “smart” controls and/or materials that capture signals and detect the movements of the user in order to control them automatically. Examples include: microprocessor-controlled prosthetic knees, which sense the position of the knee during walking and adjust the settings of pneumatic or hydraulic
cylinders to provide greater stability; and myoelectric hands, which sense signals across the surface of the skin and switch on an electric motor to open or close the hand. These products and working methods usually require a higher level of expertise than basic and intermediate products. They are also usually more expensive; however, some manufacturers are adopting more rational production processes in order to reduce overall costs, so that some will become appropriate for low-income settings.

Working methods are sometimes linked to a certain product level but are usually not. For example, computer-aided design, manufacturing tools and equipment that allow scanning of body segments and automated manufacture, such as 3D printing of prostheses, orthoses, components and models (see Box 9), can be used for products at all three levels. Introduction into a service of any new product, component, material, equipment or method (at basic, intermediate or advanced level) must be accompanied by specialized training for both clinical and technical personnel; without it, the product might not be used to its full potential, the financial investment might be lost, and the safety of the user might be jeopardized.

**Box 9. 3D printing of prostheses and orthoses**

Computer-aided design and manufacturing techniques have been used for several decades in prosthetics and orthotics to design and carve shape-captured models of body segments; however, “3D printing” has brought new opportunities for upgrading conventional fabrication. Only in the past two decades has the additive process of printing of thin layers of material (usually thermoplastics) been applied to prosthetics and orthotics. This is a much cleaner technology, as plaster casts or moulds are not required. It is less traumatic for users, especially children, and the devices take less time to produce (29). 3D printing usually involves exposure to a 3D scanner that captures all the dimensions of the body segment. Pictures from different angles are digitally stitched together to make a 3D image data file, which can be sent to a 3D printer.

The 3D technique can be used to fabricate custom devices or component parts (29, 30). Developments in materials and technology mean that prosthetic sockets, orthoses and components are becoming strong enough to withstand ISO testing and normal day-to-day use; the field of 3D printers is now large enough to print full-length prostheses and orthoses; and the capital investment for scanners and printers is falling as the demand increases. This is not, however, the solution for everyone everywhere. Prosthetics and orthotics clinicians should have a clear understanding of the use and benefits of 3D printing as compared with the conventional processes for making orthoses or prostheses.

With training of appropriately skilled personnel and strengthening of all core components of prosthetics and orthotics services, 3D printing and other technological advances offer solutions for increasing access to prostheses and orthoses for the nine in ten people who currently have no access and for increasing user choice and experience in existing services.

**2C Prefabricated and custom-made products**

Prosthetics and orthotics service providers usually use both prefabricated and custom-made products. Both types must be fitted and adjusted to conform to the anatomical features of the user. The choice of product should be guided by an evaluation of the likelihood of achieving a good fit, comfort, function, safety and quality, as well as cost (as in evaluating the appropriateness of technologies, see 2A). The choice will be influenced by the economic
environment in which the services are provided. Both prefabricated and custom-made products may be basic, intermediate or advanced (see 2B).

**Prefabricated products**, such as certain ankle–foot and knee orthoses and many spinal and cervical orthoses, are usually available in different sizes and can be selected according to clinical criteria and measures of the user’s limb, trunk or neck (31). Many prefabricated products are designed for temporary, single use. A range of prefabricated, off-the-shelf products is also available in hospital units (such as emergency, physiotherapy and occupational therapy and podiatry departments) as well as in PHC services.

Prefabricated products may allow faster fitting and be less expensive than custom-made devices, but they may also be less effective and should be used only when satisfactory results can be achieved. Furthermore, in some situations, particularly in low-income settings, the cost of storing prefabricated products may be prohibitive and it may be more cost-effective to fabricate devices individually.

**Custom-made products** include upper- and lower-limb prostheses and orthoses and many spinal orthoses. Custom-made products are usually chosen when a closer fit, better function and/or stronger support or correction is required than can be achieved with prefabricated alternatives or where these alternatives do not exist. Custom-made products can be constructed from a wide range of materials, including plastics, metals, leather, carbon fibre and composite materials, and prefabricated components chosen and assembled according to the user’s needs. Fabrication of these products usually requires a more complete set of body segment measurements and frequently includes capturing the shape and volume of the body part and making a plaster mould and/or computer image to serve as a model.

### 2D Priority assistive products

WHO estimates that over one billion people need one or more assistive products for mobility, vision, hearing, communication or cognition. To improve access to high-quality, affordable assistive products in all countries, WHO’s Global Cooperation on Assistive Technology (“GATE”) initiative prepared a “priority assistive products” list (32) after consultation with a wide range of experts, users and caregivers. Consensus was reached on a list of 50 products, including prosthetic and orthotic products, that are considered priorities for maintaining or improving individual functioning and should be available at a price the community or country can afford.

The list is not restrictive but provides governments with a model for preparing a national list. It can act as a catalyst for governments to fulfil their commitment to ensure access to assistive products at an affordable cost, as mandated by the CRPD. The list can create public awareness, help in mobilizing resources, guide product development and stimulate competition and thus contribute to increasing access to assistive products globally. Using this model, governments can define the prosthetics and orthotics and mobility products and the
types of technology that are national priorities for meeting local needs. In view of the great unmet and growing need, such decisions will be important in moving towards universal health coverage and defining reimbursement policies, including insurance coverage (see 1J and 1K).

Of the 50 assistive products on the list, 16 are mobility devices, including six categories that reflect the core work of prosthetics and orthotics services (Table 2).

### Table 2. The 16 mobility products on WHO’s priority assistive products list

<table>
<thead>
<tr>
<th>Prosthetic and orthotic products</th>
<th>Other mobility products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower-limb orthoses</td>
<td>Canes and sticks</td>
</tr>
<tr>
<td>Upper-limb orthoses</td>
<td>Crutches</td>
</tr>
<tr>
<td>Spinal orthoses</td>
<td>Standing frames</td>
</tr>
<tr>
<td>Club foot braces</td>
<td>Walking frames and walkers</td>
</tr>
<tr>
<td>Lower-limb prostheses</td>
<td>Rollators</td>
</tr>
<tr>
<td>Therapeutic footwear (diabetic, neuropathic and orthopaedic)</td>
<td>Tricycles</td>
</tr>
<tr>
<td></td>
<td>Wheelchairs:</td>
</tr>
<tr>
<td></td>
<td>• manual for active use</td>
</tr>
<tr>
<td></td>
<td>• manual assistant-controlled</td>
</tr>
<tr>
<td></td>
<td>• manual with postural support</td>
</tr>
<tr>
<td></td>
<td>• electrically powered</td>
</tr>
</tbody>
</table>

**ISO categorization**

ISO is an independent international NGO that brings together experts to prepare international standards to facilitate international exchange and trade and to ensure quality, safety and efficiency. ISO standards cover almost every industry, from technology, to food safety, to agriculture and health care, including standards and classification of assistive products. With regard to prosthetics and orthotics, ISO standards ISO 8549 Parts 1–3, ISO 13405 Parts 1–3, ISO 8549 Part 3 and ISO 13404 are particularly important, as they specify methods and provide terminology for the categorization and description of products and components (33–37). These standards should be used for any national classification of prosthetic and orthotic products. (See 4P, Box 26, for other ISO terminology standards.)

**Supply of components and materials**

Procurement of material and logistics are important tasks of a prosthetics and orthotics service provider and must be well managed to ensure that services are cost-effective and uninterrupted (38). In large organizations, this work may be done by a dedicated procurement office; in smaller service units, the responsibility may be delegated to regular staff members.

**Importation of material**

Components, materials and consumables (including off-the-shelf products) used by a prosthetics and orthotics service provider may be either imported or purchased locally. While
many basic materials, such as some plastics, plaster of Paris, wood and leather, are readily available in most countries, certain components and materials must be imported.

Importation of components and materials for prosthetics and orthotics services is often difficult, particularly in low- and middle-income countries where customs clearance may be long and expensive, ultimately reducing the number of people who can be assisted. National stakeholders should work with relevant authorities and ministries to ensure that components and materials used exclusively for the fabrication of prostheses and orthoses are exempt from import taxes and customs fees and that importation procedures are simplified.

**National distribution of components and materials**
Prosthetic and orthotic components and materials are usually ordered directly from suppliers by each service provider. In some countries, the existence of a national procurement office and central store may facilitate the process for individual service units and make it more cost-effective. When services are integrated into the health system, the central store should be part of the medical supplies department of the health ministry. In other cases, it may be an independent entity serving service units in part of the country, the whole country or several countries. By placing bulk orders to suppliers, a central store can facilitate importation procedures and reduce costs for individual service units.

**Stock management**
With appropriate stock management, prosthetics and orthotics service providers can ensure that service is not interrupted because of a lack of materials or spare parts for machines or other equipment and can avoid overstockage. Effective planning is needed to ensure that all materials are in good condition and available when needed. Computer software can be used to manage stock efficiently, record and analyse stock values, prepare purchase orders and calculate service costs, including the unit costs of different types of treatment (see 1E, Box 2). In large and medium-sized service units, the responsibility for stock management should be assigned to a storekeeper. Stores should be separate from other workshop areas.

**Donated components and materials**
Some prosthetics and orthotics service providers are supported by organizations or enterprises, which, instead of making financial contributions, provide in-kind donations of components and materials for the fabrication of prostheses and orthoses. While such donations can directly increase productivity, the donated items must meet the standards of the service provider and be considered the most appropriate. Service providers should be permitted to influence the types and quantities of components and materials that are donated to ensure that they correspond to their needs.

**Reuse of components**
Prosthetic and orthotic components are sometimes reused in order to reduce costs and assist more people. When this practice is allowed, it should be regulated by the State (see 2G), and the safety of users must not be jeopardized. Used products should be refurbished by a licensed operator under controlled conditions, and the items must be decontaminated and approved.
before they are reused. The process should be documented, and users must be informed when reused components are integrated into their prostheses or orthoses. (Customized parts, such as prosthetic sockets, should not be reused under any circumstances.)

**Donations of used prostheses and orthoses**

Service providers in high-income countries sometimes collect old prostheses and orthoses and donate them to low- and middle-income countries. Although the intention is admirable, this practice is not always helpful. In the worst case, it may corrupt the efforts of national stakeholders to establish sustainable and affordable services over which they have control.

As all prostheses and many orthoses are custom-made, it is unlikely that a donated item will fit another user. While some components of a disassembled device can be reused, they may be of a different type from those usually used and cannot be combined with local technology. If technical personnel have not been trained in the new technologies, the service provider may store components that will never be used and will eventually have to be disposed of, involving cost, time and resources.

In-kind donations of second-hand prostheses and orthoses will be of value only when done in a coordinated, professional way. There must be close communication to ensure that the receiving provider has the capacity to use the technology, the quality of the reused components must be controlled (see above), complete sets of items should be supplied, and the results should be followed up. Donations should not undermine the national market or the work of other service providers who do not receive material for free.

**Waste material**

Prosthetics and orthotics services, like most manufacturing industries, generate waste, some of which may be harmful to the environment. Limiting waste material in the production process is in the economic interest of the service provider and in the environmental interest of society. Waste products and materials should be properly disposed of according to national rules and regulations; the handling of hazardous products should be monitored closely. Users should return their prostheses and orthoses to the service provider when they are no longer using them. Devices should be disassembled, certain components reused if possible (see above) and the remainder disposed of according to the recommendations for each type of material.

**2G Regulation of technical issues**

Prosthetics and orthotics service delivery should be regulated by the State to ensure that users have access to high-quality products, minimizing the availability of substandard products that are unsafe or ineffective (see Regulation in 1B). Regulation of the technical aspects of service delivery includes monitoring the quality of products, materials and equipment. Regulations should, for example, apply to product and component supply, importation of materials for prosthetics and orthotics production and reuse of components (according to legislation for the reuse of health products, see Reuse of components in 2F). Where appropriate, ISO standards should be applied (see 2H).
2H Structural and clinical testing

Prosthetic and orthotic components and materials must be durable, so that sudden, unexpected failure of a device does not result in injury to the user. Structural and clinical field tests should be conducted to determine the strength, durability, lifespan and biocompatibility of components and products.

**Structural testing** of prosthetic and orthotic components and materials is conducted in a laboratory environment according to ISO specifications, such as ISO 10328, which lists the procedures for testing the static and cyclic strength of lower-limb prostheses (39). Use of standardized procedures allows comparisons of different types of component parts, such as prosthetic feet, indicating their quality and cost-effectiveness. Components manufacturers should always test new technologies before placing them on the market in order to demonstrate their compliance with national and international standards.

**Clinical field tests** should complement structural testing to determine the strength, durability, functionality, safety and effectiveness of prosthetic and orthotic components and products in normal use. The environment in which prostheses and orthoses are used varies widely throughout the world. The conditions in many low-income settings, with rough terrain and hot, humid weather, may test components especially. To understand the impact of such conditions on the strength and durability of a product and to compare alternative technologies, systematic user trials can be conducted in the field. Clinical testing, like
structural testing, should adhere to certain rules: user trials should always be undertaken in accordance with national ethical regulations; participation must be voluntary, with formal informed consent by the individuals to participate in the test; and tests should follow national and international scientific standards to ensure the reliability of the results.

In addition to testing, the quality of prosthetic and orthotic products and services should be ensured by the establishment of quality management systems at service level (see 4R).

21 Technical and clinical research

Research at global level
Research is critical for the development of prosthetics and orthotics services. While research in this field is conducted continuously, most of it benefits users and services in high-income countries, while less attention has been paid to the needs in low- and middle-income countries (see 2J). Furthermore, unlike many other health specialities, relatively little research is documented or published. There is thus limited evidence for the appropriateness of prosthetic and orthotic technologies, working methods and treatments, their effectiveness and cost-effectiveness. While service providers, service users and independent observers view prosthetics and orthotics treatment as important, considerable research is still required to verify this view objectively.

WHO has identified five research areas of particular importance for assistive technology (see Box 10). International organizations and academic institutions working with relevant national partners should stimulate research in these priority areas. They should also explore and implement appropriate methods for international exchange, so that results can be shared and thus benefit services in all parts of the world.

Box 10. WHO global priority research agenda for assistive technology

The WHO Global priority research agenda for improving access to high-quality affordable assistive technology (40) was prepared by WHO’s GATE initiative with more than 100 experts in assistive technology. It invites states, researchers, donor agencies, user groups, civil societies and other stakeholders to initiate and/or support research in five priority areas:

1. Effects, costs and economic impact of assistive technology
2. Assistive technology policies, systems, service delivery models and best practices
3. High-quality, affordable assistive technology
4. Human resources for the assistive technology sector
5. Standards and methods for the assessment of assistive technology need and unmet need

Specific research questions have been identified in each priority area. By addressing these, the international prosthetics and orthotics community can operationalize targeted research in the field.
Research at country level
Where relevant, research should be carried out at national centres of excellence, by establishing links with prosthetics and orthotics training programmes in academic institutions and coordinating research initiatives with national and international stakeholders. Systems should be in place to support training in research for relevant personnel at academic institutions. Prosthetics and orthotics service providers should be expected to gather data routinely and share them with researchers.

2J Development of affordable products
Components, materials and consumables for prosthetics and orthotics services are produced by many suppliers in different parts of the world at various operational scales. As in many other technical fields, most research and development in prosthetics and orthotics is conducted by enterprises driven by market demand rather than need. While this research has contributed greatly to improving prosthetic and orthotic technologies over time, the focus has been on products for high-income settings and less research had been done on the requirements of low- and middle-income countries, where the financial incentive is much smaller or inexistent. The sheer size of the market in low- and middle-income countries should, however, be an incentive for suppliers. Some attempts have been made by commercial enterprises to develop basic products. International organizations have also developed more affordable technologies, which are used in many low- and middle-income countries. In the same regions, some service providers produce affordable components of similar types.

Nevertheless, there is clearly scope – based on a very tangible global need – for alternative affordable designs that significantly reduce costs and dramatically increase the number of people who can be assisted in poorer settings. This could open new business opportunities, with mass production of cost-effective, good-quality components to meet the global need. As has been done for medicines, assistive products can be made that are affordable. This will require the involvement of many national and international stakeholders, including prosthetics and orthotics experts, private entrepreneurs, governments, service providers, representatives of users, international organizations, funding agencies and investors.
Area 3. Personnel

3A Service unit personnel

The three main categories of prosthetics and orthotics personnel are: prosthetists and orthotists, associate prosthetists and orthotists and prosthetics and orthotics technicians. Prosthetists and orthotists and associate prosthetists and orthotists are collectively referred to as prosthetics and orthotics clinicians, who mainly perform clinical work, while prosthetics and orthotics technicians and other support personnel are referred to as nonclinicians.

Prosthetists and orthotists

Prosthetists and orthotists are health professionals with overall responsibility for prosthetics and orthotics treatment, who can supervise and mentor the practice of other personnel. They are clinicians trained to assess the needs of the user, prescribe treatment, determine the precise technical specifications of prostheses and orthoses, take measurements and images of body segments, prepare models for the manufacture and fit of devices and evaluate treatment outcomes. They should have adequate understanding of the complete fabrication process in order to guide and supervise the work of prosthetics and orthotics technicians and support personnel. Prosthetists and orthotists have comprehensive training providing a broad range of clinical competence. After graduation, they should increase their experience and expertise in order to assume leadership, advance models of service delivery and participate in research and evidence-based practice. They may also continue their education to masters and doctorate levels.

Associate prosthetists and orthotists

Associate prosthetists and orthotists share many of the attributes of prosthetists and orthotists and do similar clinical work but have more limited competence and conduct less research and advancement of service delivery methods and models. Associate prosthetists
and orthotists should be supervised by a prosthetist or orthotist and have a delegated scope of practice (41). Like prosthetists and orthotists, associates supervise the work of nonclinicians and should have a thorough understanding of all technical work.

**Prosthetics and orthotics technicians**
The work of prosthetics and orthotics technicians is to fabricate prostheses and orthoses. Following the technical specification prepared by the clinician and working under the clinician’s supervision, the technician processes materials, assembles components, makes the product ready for fitting and finishes the product for final delivery. Technicians know the materials, technical processes and safe practice involved in prosthetics and orthotics and provide repair and maintenance services.

Under controlled circumstances, these technicians may support prosthetists and orthotists and associates in certain aspects of clinical work in order to increase access to services. This work must follow an agreed protocol, be done under the close, continuous supervision of a clinician, within clearly defined limits and only after adequate skills and competence have been acquired in relevant areas. The technician must know when to refer back to the supervising clinician for review.

Developing the role of technicians, thereby alleviating clinicians of the work of manufacture, will reduce bottlenecks in services due to the limited availability of qualified professionals (see 3G and 3H, Box 12).

**Support personnel**
Support personnel include workers with no formal training in prosthetics or orthotics, who have nonclinical duties that are essential for the overall result, such as plastic-forming or plaster work. Other support personnel include storekeepers, cleaners and maintenance workers.

**Administrative personnel**
The care pathway of users involves communication and interactions with reception and administrative personnel at the first appointment and follow-up of service delivery. While no specific knowledge in prosthetics and orthotics might be required for this work, reception personnel must be skilled, competent and at ease with users and caregivers to ensure that the services are user-centred (see 4A). The way in which users are received can positively influence their rehabilitation. Long-term service users in particular will become known to reception personnel over time, and friendly relationships should prevail. Targeted training of administrative personnel may be required to ensure the highest quality of services.

The appointment of users to administrative roles can be beneficial, as it offers opportunities for peer support, in particular to first-time users.
3B Other professionals on the team

Medical specialists often play a central role in the provision of prosthetics and orthotics services as members of a multidisciplinary rehabilitation team (see 3C) and in referring users to the services. Of particular importance are physicians specialized in physical and rehabilitation medicine (particularly for rehabilitation of people with amputations or in complex care), amputation surgery, orthopaedics, vascular surgery, general surgery, neurology, rheumatology, plastics and reconstructive surgery, paediatrics and geriatric care.

Physiotherapists and occupational therapists are critical to the outcome of prosthetics and orthotics service delivery and should be permanent members of the multidisciplinary rehabilitation team (see 3C). Of particular importance are those specialized in amputation rehabilitation, stroke, cerebral palsy, clubfoot treatment and spinal conditions. Other allied health professionals important in prosthetics and orthotics services include podiatrists, pedorthotists, pedorthists, psychologists, biomedical engineers and pharmacists.

Other personnel – such as health personnel, social workers and CBR workers – may assist in the provision of services and work within an agreed protocol with appropriate supervision, provided they have sufficient training. They also frequently refer potential users to prosthetics and orthotics service units.

3C Multidisciplinary rehabilitation teams

In complex cases and long-term treatment, prosthetics and orthotics services should be offered by a multidisciplinary rehabilitation team with defined common goals and a shared team identity. Together, they assess users to determine their needs, prepare holistic treatment plans and evaluate the outcome of treatment. Multidisciplinary teams should have an appropriate mix of skills and include a prosthetist or orthotist, a physician, a physiotherapist, an occupational therapist, a nurse, a psychologist and a social worker. The user (and, where relevant, families and caregivers) should also be regarded as members of the team and be allowed to influence any decision taken (see 4A). Ideally, the team members meet at the time of the assessment and at the end of treatment and carry out agreed interventions according to their roles. Particularly in poorer settings, the team may be smaller, consisting only of the user and one rehabilitation professional. While not all prosthetics and orthotics treatments require interventions by other specialists, efforts should always be made to contact other specialists in more complex cases.

Teamwork provides an opportunity for team members to learn from one another. In well-established multidisciplinary teams, tasks can be shared and shifted among team members of different professions. This can alleviate the pressures of busy services and make them more cost-effective. Task-shifting may include having a nurse supply simple ankle foot orthoses, if the scope of practice has been agreed and sufficient training provided. Personnel must follow an agreed protocol and be supervised directly or indirectly by a prosthetist or orthotist.
3D Training of prosthetics and orthotics personnel

Training of new personnel should be dramatically increased to ensure equitable access for everyone in need, and higher training should be available for those who wish to teach. Training must be conducted in parallel with expansion of services, so that personnel who are trained have employment.

The numbers of prosthetics and orthotics courses at different levels and the numbers of trained professionals have increased significantly during the past few decades, particularly in low- and middle-income countries. Although courses may not yet be available in all countries, many prosthetics and orthotics schools have an international intake, so that professionals from essentially all the countries and areas of the world can be trained. This important development has been made possible with financial and technical support from the international community. Although there are still not enough professionals to cover the need, they represent a foundation for extending high-quality prosthetics and orthotics services globally.

General aspects

Prosthetics and orthotics training programmes should preferably be an integral part of a tertiary educational institution in the national health education system and be offered with courses for other rehabilitation professionals, such as physiotherapists and occupational therapists. Education in prosthetics and orthotics is a combination of theory and practical training in the health science and engineering. Typically, theory and technical practice are taught alternately in a classroom during the first part of the programme, after which, prosthetist and orthotist and associate prosthetist and orthotist students are usually introduced to clinical practice with users in a safe, controlled clinical environment in the educational facility. This practice helps to develop skills in assessment, fitting and alignment with the latest evidence-based techniques. This phase is followed by supervised practice placements to further develop practical skills.

The training of prosthetics and orthotics technicians focuses on product preparation and the use of different materials, tools and machines.

Training levels

To meet national demand and ensure that everyone everywhere has access to prosthetics and orthotics services, various levels of training should be available in a country. While this may be difficult in some countries, a cost-effective solution might be for countries in a region to share opportunities for training.

Prosthetists and orthotists usually have at least a bachelor degree, like other health and rehabilitation professionals such as physiotherapists and occupational therapists. The entry requirements should meet national criteria for tertiary education, which should include completion of secondary education. To further develop the profession, prosthetists and orthotists should be encouraged to complete post-graduate studies, like their colleagues in other health and rehabilitation services.
Associate prosthetists and orthotists should attend training at further education level, with entry requirements aligned with other vocational training in their country and selection criteria similar to those of prosthetists and orthotists.

Fully trained prosthetics and orthotics technicians usually attend training at further education (vocational) level corresponding to the level of health care assistants and assistant therapists or have equivalent experiential learning.

The training pathway should be planned as a continuum, so that prosthetics and orthotics personnel can continue to higher levels of training. Thus, talented, dedicated technicians can progress to clinical positions with more responsibility, and associates can become prosthetists and orthotists. A few training programmes exist that allow upgrading from one level to another. More options for academic progression should be in place in each training institution to increase access to education.

**Modes of teaching and learning**
The modes and methods of training programmes depend on the local educational culture and learning environment. The two disciplines – prosthetics and orthotics – are sometimes taught separately or may be combined, with a joint degree awarded.

Theoretical training is usually provided full-time according to a schedule in a school environment but is sometimes done part-time or as an online or distance-learning course. Modular courses, with examinations after each completed module, have proven to be effective. Training can also be provided by blended learning, which usually includes online theory and face-to-face technical and clinical practice at a central location, where the theoretical knowledge can be applied and practical skills developed. This training mode allows participants to stay on the job and continue service delivery while undergoing training. It can help practitioners without previous formal training to have a recognized education and others to upgrade to a higher educational level. This type of training can be particularly useful in emergency contexts and in countries where there are only a few prosthetics and orthotics personnel, who cannot be released from their jobs for full-time training.

An interdisciplinary approach to teaching and learning for prosthetics and orthotics, therapy and medicine in shared training sessions can stimulate teamwork among graduate health and rehabilitation professionals. This is particularly important in practical clinical training, especially when students study assessment and prescription and evaluation of treatment, and can also be used for training in common theory subjects.

**Educational standards**
Professional standards for prosthetists and orthotists, associates and technicians are well established, published and upheld by national professional bodies and by ISPO. They can be used by policy-makers, government ministries, regulatory bodies or funding agents as a benchmark for education and a guide for curriculum development. WHO, in collaboration with ISPO, has prepared detailed education and training guidelines for the prosthetics and
orthotics professions, which are widely accepted by governments and nongovernmental agencies in the field. To guide the establishment (or restructuring) of prosthetics and orthotics training courses, ISPO has information packages that describe the learning objectives for each type of course, with a syllabus and appropriate arrangements for final examination. The packages also outline arrangements for evaluation and international recognition of prosthetics and orthotics training programmes.

Course content
Prosthetics and orthotics training should follow the educational standards set at international and national levels, including those of ISPO. Theoretical training typically includes clinical subjects, such as anatomy, physiology, prosthetics and orthotics science, pathology and orthopaedics, as well as technical topics, such as mechanics, biomechanics, materials science and technology. Practical training usually provides broad understanding of prosthetics and orthotics technologies, components, materials and clinical work. Instructors should ensure that the theoretical knowledge is translated into skills in design, production, adaptation and alignment of prostheses and orthoses, which are directly relevant to the functioning of the product and the comfort and safety of the user. Quality considerations must be emphasized.

Prosthetics and orthotics students should build problem-solving skills and become reflective practitioners, willing to learn from their day-to-day and case-by-case experience and to view continuous learning as part of their professional life. It is also important to emphasize professional communication skills.

Prosthetics and orthotics courses should also provide fundamental knowledge of:

- the concepts of user-centred care, user policy and user rights (see 4A, 4B and 4C);
- disability issues;
- multidisciplinary teamwork;
- professional codes of conduct and ethics, with clearly definition of the role of the professional and the limits of appropriate professional behaviour (see Box 11);
- management issues and tools, such as those for cost calculation, cost–benefit analysis, user management, stock management and quality management;
- work safety;
- referral processes;
- the national health care system and rehabilitation services;
- provision of other mobility assistive products, such as wheelchairs and crutches, which are often prescribed with prostheses and orthoses;
- clinical research, technical development and innovations; and
- community development in relation to prosthetics and orthotics, rehabilitation and health care services.
All professionals who work with users must have and uphold a professional code of conduct and ethics. This is true for prosthetists and orthotists and associates. The 15 standards of proficiency of prosthetists and orthotists of the Health and Care Professions Council of the United Kingdom (42) provide a good example of professional codes of conduct and ethics.

1. Be able to practise safely and effectively within their scope of practice.
2. Be able to practise within the legal and ethical boundaries of their profession.
3. Be able to maintain fitness to practise.
4. Be able to practise as an autonomous professional, exercising their own professional judgement.
5. Be aware of the impact of culture, equality and diversity on practice.
6. Be able to practise in a non-discriminatory manner.
7. Understand the importance of and be able to maintain confidentiality.
8. Be able to communicate effectively.
9. Be able to work appropriately with others.
10. Be able to maintain records appropriately.
11. Be able to reflect on and review practice.
12. Be able to assure the quality of their practice.
13. Understand the key concepts of the knowledge base relevant to their profession.
14. Be able to draw on appropriate knowledge and skills to inform practice.
15. Understand the need to establish and maintain a safe practice environment.

**Selection of students**

Students for professional training in prosthetics and orthotics should be selected transparently, without discrimination, guided first and foremost by academic criteria. Students must have sufficient educational qualifications to ensure that they can fully assimilate the course content and become competent in their profession. A number of further considerations will ensure that the right individuals are trained. Students should, for example, have an aptitude for clinical and technical work and have the right values and attitudes to working with people with disabilities.

Globally, more men than women are trained as prosthetists and orthotists. This risks limiting the access of women to services. Service units should have balanced numbers of female and male personnel at all professional levels so that users can choose a female or male clinician if they so wish. Special initiatives and advocacy may be needed to ensure that sufficient numbers of women undergo training and have opportunities for employment equal to those of men.

To ensure access to services by diverse groups, there should be a good balance in the student intake with regard to culture, ethnicity, faith, gender and other demographic factors. It may be appropriate to select students from areas where a new workforce is needed, particularly for remote and rural locations. This will ensure they know the local language and customs and are motivated to work in such settings. This may generally increase the retention rates of newly trained individuals (see 3I).
People with disabilities, users of prosthetics and orthotics services in particular, should be encouraged to apply for all training, as appropriate. People with experience of disability on the workforce can provide good role models for users and generally assist in changing negative attitudes. Their inclusion may require special arrangements: preparatory training may have to be provided so that people with disabilities can meet the entry requirements; the learning environment might have to be adjusted; and advocacy may be required to make sure they have equal opportunities for employment (28).

Newly qualified graduates
After successfully passing the final examination, graduates will usually be awarded proof that they have completed training for an appropriate qualification. The newly trained professional will lack experience, which will be built through reflective practice on the job and CPD (see 3F) throughout their working life. Graduates should also either complete an internship or have extensive supervised clinical practice as part of their training before they obtain national accreditation and certification and are authorized to practise independently.

During the early years of professional practice, graduates usually provide a defined range of treatments for users with different diagnoses. Service providers should identify senior professionals who can assume supervision and mentoring responsibilities, which may require building these skills.
Training abroad

Prosthetics and orthotics education programmes are not available in all countries, and it may be difficult to justify the establishment of a school in small countries where only a limited number of personnel are needed. One solution is to train professionals abroad at a school with an international intake. Training prosthetics and orthotics personnel abroad is usually a significant financial investment for a relatively small number of trainees. These individuals must therefore be selected with care (see above) so that the investment yields long-term results, in particular if there is a scholarship. Graduates should be able to enter the job market swiftly on their return home, so there should be jobs for them to return to. This may require policy-makers to create posts or provide the necessary resources. It is important that certificates and diplomas obtained abroad are recognized in the home country; national recognition is often lengthy and might have to be initiated before training commences.

Training abroad has the advantage of exposing students to different contexts and working methods and providing opportunities for establishing regional and international professional contacts. It may, however, give limited clinical practice in the context in which the professional will be working at home. International training institutions should make sure that the skills that are taught are relevant to different local contexts by including the impairments and conditions that might be seen in service units in other countries.

New graduates returning from international institutions will require support from more senior, experienced colleagues to enter the profession fully. Where such professionals are not yet available, graduates might have to be supported by international prosthetics and orthotics professionals, for example through volunteer placements, consultancies or work exchange.

3E Training other professionals in prosthetics and orthotics

Prosthetics and orthotics are distinct fields of knowledge that demand specific training and development for all people involved in service provision and related health care and rehabilitation. To ensure competence across the workforce, health, allied health and social care professionals should be given an overview of prosthetics and orthotics subjects in their professional training programmes. This information should be as pertinent as possible, and training should preferably include study visits to prosthetics and orthotics service units. Professionals such as therapists, orthopaedic, neurological and vascular surgeons and physicians specializing in physical and rehabilitation medicine require more in-depth knowledge of prosthetics and orthotics. Prosthetists and orthotists should work with medical faculties and educational institutions to ensure that the course content is appropriate. They might also be involved in preparing targeted training modules and participate as lecturers in direct training.

After their graduation, some health, allied health and social care personnel will work with prosthetics and orthotics service units in the treatment of related diseases and health conditions, and some will be directly involved in prosthetics and orthotics service delivery.
They will therefore require more training in these subjects, from basic sensitization to highly specific knowledge for relevant specialists. This can be provided in special courses and seminars and by experiential learning, such as in multidisciplinary teamwork, which allows continuous exchange of information. Prosthetics and orthotics professionals and service providers should establish regular working contacts with partners in health, social and education sectors to make sure they have the essential knowledge and skills for referral and follow-up.

When prosthetics and orthotics services are part of the health care system and certain tasks are shifted to doctors, nurses and other PHC personnel, these must have sufficient training and supervision. Training material and tailored courses should be prepared for different personnel categories, taking into account their professional training and their intended function in the service delivery system. Prosthetics and orthotics professionals at national and international levels, with colleagues in health and education sectors, have a significant role in preparing such training.

**3F Continuing professional development**

Service providers should ensure that all personnel are given opportunities for CPD to maintain, update and further strengthen their competence at all levels. This improves the quality, effectiveness and efficiency of the services and ensures inclusion of new developments in clinical and technical practice, including new technologies. CPD can also develop the role of professionals, extending their knowledge into new fields or specializing in more narrow fields (see 3G).

CPD pathways may be a mixture of formal and informal learning. The formal pathways include short courses for upgrading personnel from one level to another through a framework in which training levels are aligned with career progression. Courses may go beyond core prosthetics and orthotics subjects to include training in related health conditions, such as diabetes and cardiovascular diseases.

Informal CPD pathways build knowledge, skills and competence in learning that is integral to professional practice. Informal CPD opportunities include:

- reflective practice (individual reflections on everyday practice);
- sharing experiences with team peers;
- evidence-based practice (learning from audit case series, audit and research results);
- case conferences and ward rounds (multidisciplinary review of single cases);
- reviews or focus groups by users; and
- participation in seminars, conferences and workshops (which may be multidisciplinary, highlighting the interrelationship between different professions).
Many experienced clinicians with empirical training or clinicians who are associate prosthetists and orthotists have not learnt how to find information or appraise research and might require guidance. To ensure conditions for continuously increasing knowledge, scientific literature should be accessible in the service, with training in literature searching and appraisal, so that clinicians can be efficient and self-sufficient in accessing information on which to build their practice. Until recently, information was found in a library in some service units, but the Internet makes it possible to access full-text journal articles online or offline with regularly updated sources, such as the WHO Hinari e-Granary system and open source journals. Support to ensure that personnel have access to information can be provided in the form of computer hardware and software. A more vibrant culture of information use can be guided by sharing evidence-based case studies and developing evidence-based treatment protocols within the prosthetics and orthotics team.

Service providers can also mentor personnel to increase their competence, either face to face or through an e-health approach whereby a mentor is matched to selected personnel to analyse a case study. This kind of CPD can help to embed new skills and knowledge after a short course; for example, a mentor may continue supervision of a series of prosthetics and orthotics treatments, until the recipient is competent and confident in the new techniques.

Prosthetics and orthotics personnel should always be willing to learn and be committed to CPD and reflective practice. A certain amount of CPD per year should be a compulsory component of their employment. More experienced personnel should participate in annual professional development planning, when they are given responsibility to identify their CPD needs and work in partnership with their employers and professional associations to agree and implement individual professional development plans.

### 3G Role development

Prosthetics and orthotics training courses can provide the knowledge to start practising the profession, but no graduate will have all the knowledge and skills required to fully master all fields and sub-fields. That is learnt by experience in day-to-day practice, with colleagues, mentors and occasional courses and seminars (as part of CPD, see 3F).

The role of prosthetics and orthotics professionals therefore develops over time; it should match the needs of the service and the competence of other rehabilitation team members. Not all personnel in a unit will deliver all types of service. In large units in particular, the roles of professionals can be differentiated so that they specialize in narrower areas (such as upper-limb prosthetics, diabetic footwear, sports injuries). This will increase their proficiency and enable the unit to offer services of higher quality in a wider range of fields while also minimizing the resources required for additional training, as not all personnel need to be trained in all fields.
Roles can be developed within the employee’s usual professional boundaries, by specializing in distinct fields of prosthetics and orthotics, but also outside these boundaries. Prosthetists and orthotists can broaden their knowledge by assuming certain tasks in a multidisciplinary team (see 3C) or by extending their responsibilities to management, such as monitoring and evaluation, or research. They may also advance their practice with a master’s degree or doctoral level training. A prosthetics and orthotics technician may be given additional training to take on some of the role of a prosthetist, orthotist or associate, provided sufficient monitoring is in place.

Role development can increase productivity and the quality and range of services and can be a means of distributing tasks across the workforce. This may relieve overloading of personnel and avoid bottlenecks in service delivery. For the individual, role development may be an important incentive; he or she may be motivated by having more responsibility or functioning as the unit’s focal point and specialist for a defined field or in multidisciplinary work, all of which are signs of recognition.

Role development should be considered when setting goals in professional development plans (see 3F).

**3H Workforce planning**

The workforce must be planned to ensure the right numbers of personnel with the right competence at the primary, secondary and tertiary levels of service delivery. The plan should guide training, so that adequate numbers of professionals are available; there should not be more than can be absorbed, as this would waste financial resources, and not too few, which might result in interruption of services.

Workforce planning involves four steps (Fig. 2): determining the actual size and nature of service needs, calculating the full need for personnel, profiling the existing workforce and determining any gaps between future demand and current supply of personnel. The workforce development plan should be designed to address any gaps.

**Fig. 2. The four steps in workforce planning**

1. Determining the need for services
2. Determining the need for personnel
3. Profiling the existing workforce
4. Determining the need for training
Determining the need for services

The ways in which the need for prosthetics and orthotics services can be determined or estimated are discussed under 1N. The size, geographical distribution and type of services needed then form the basis for calculating the required workforce. Future requirements can be estimated from growth or changing patterns in the population of users, such as how fast the population is growing, an increase in noncommunicable diseases or a situation of conflict.

Determining the need for personnel

The need for personnel can be calculated from the estimated need for services and local factors, such as the types of services required and the geographical distribution of service units. An average country can be expected to require 5–10 prosthetics and orthotics clinicians per million population and a higher number of nonclinicians (see Box 12).

Box 12. Numbers of prosthetics and orthotics personnel required

The numbers of prosthetics and orthotics clinicians (prosthetists, orthotists and associates) and nonclinicians (prosthetics and orthotics technicians and support staff) are determined by factors such as the need; the organization of service systems and units (geographical distribution and whether services are centre-based or decentralized); the type and range of products provided (e.g. technology, complexity, proportions of prostheses and orthoses); the knowledge, skills and attitude of personnel; and the financial context.

Clinicians

On average, a country requires 5–10 prosthetics and orthotics clinicians per million population, although data and evidence are lacking. In high-income countries, the number of clinicians is usually higher, at 15–20 per million population or more in some countries. In low-income countries, the number may be as low as 1 per million population, complicating the provision of sufficient services of appropriate quality.

In a standard prosthetics and orthotics service unit, a clinician (supported by nonclinical personnel) can be expected to provide complete services to 300–600 users per year (including first provision, renewals, follow-up and maintenance and repairs). The number of users who can be assisted depends on the type and complexity of treatments. International comparative data are needed for more accurate figures.

Nonclinicians

Each clinician is normally supported by 2 nonclinicians, so that a country would need some 10–20 nonclinicians per million population. Assistance by 4–5 nonclinicians allows more users to be treated per team, and this is important in settings where there are few trained professionals, particularly in smaller, decentralized service units. Increasing the ratio of nonclinicians to clinicians is an economical way of developing services until more clinicians can be trained. In contrast, for specialized services (at tertiary level or in designated specialist clinics), a lower ratio of nonclinicians to clinicians, such as 1:1, is usually more appropriate.

Minimum requirements

Each service unit should have at least one qualified prosthetist and orthotist. In countries where there are few professionals, the quality of clinical services should be assured by an experienced associate prosthetist or orthotist with the support and supervision of a prosthetist and orthotist.

In workforce planning, the fact that at least two to four times more people require orthotic treatment than prosthetic treatment (43) should be considered. Clinicians who work in small service units and are the only qualified professionals available should usually be trained in both disciplines. In units in which responsibility can be assumed by several clinicians, specialization in either discipline is usually sufficient.
Projections should be made for the short and the long term, for example 5, 10 and 15 years ahead, so that future development is adequately taken into account. Workforce planning should preferably correspond to the cycle of national population censuses.

For a workforce planned to function at primary, secondary and tertiary levels, calculations should include other disciplines that contribute to prosthetics and orthotics service delivery, such as physicians, health and rehabilitation professionals, PHC personnel and others applicable to the local context.

**Profiling the existing workforce**
An audit of the entire workforce should be conducted to determine its profile, such as the numbers, age, gender and professional experience.

**Determining the need for training**
Training needs can be determined by comparing the numbers and disciplines of the available personnel with the numbers required, keeping in mind that the workforce should be gender-balanced. This will reveal the numbers who should be trained, where they are needed and the type of training required. The estimated numbers will, however, often have to be adapted...
to practical and financial realities. Training must be affordable, and graduates must find a place in the service system. Thus, often, not all training can be provided at once. There should be strong links between service providers, training institutions and planners to ensure that prosthetics and orthotics workforce planning corresponds to that in the general health and welfare sector.

3I Retention of personnel

As training and mentoring of prosthetics and orthotics personnel is a substantial financial investment, it should yield long-term results, and strategies are required to motivate professionals to engage fully in service.

First, the right students should be selected for training and they should be genuinely interested in working in the profession (see Selection of students in 3D). In addition, the employer and the service delivery system should provide stimulation. The motivation of the workforce is linked to, for example:

- proper and equitable recognition of the profession (see 3K),
- career possibilities,
- salary levels and employment benefits,
- working environment,
- the range of responsibilities given,
- possibility of influencing decisions in the work-place,
- positive leadership and
- factors linked to the image of the profession (see 1R).

The migration of prosthetics and orthotics professionals from poor to rich countries and from rural to urban areas is a particular problem. In low- and middle-income countries especially, prosthetics and orthotics graduates sponsored by a scholarship may choose to leave their work place or country for more favourable conditions elsewhere. This can disrupt services, and, even if the skills of the graduates are used, they will not benefit the intended services. The situation is sometimes addressed by establishing an “employment bond”, for example obliging graduates to work for five years with a certain service provider; however, bonds may be broken and skilled human resources lost. Potential employers of prosthetics and orthotics personnel in the first five years after graduation should therefore determine whether they have signed an employment bond. Sponsors, employers and training institutions might jointly prepare a code of conduct for recruitment and retention of graduates on scholarships to ensure that the initial investment in a country or region benefits that area.
Various measures can be taken to stimulate the interest of students and personnel in working in remote and rural areas and ensuring their retention. Table 3 lists a number of possibilities that have been proposed.

Table 3. Measures that might improve the retention of prosthetics and orthotics personnel and make them more interested in working in remote and rural areas

<table>
<thead>
<tr>
<th>Area</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>• Attract the “right” students.</td>
</tr>
<tr>
<td></td>
<td>• Select students from rural areas.</td>
</tr>
<tr>
<td></td>
<td>• Train students close to rural communities.</td>
</tr>
<tr>
<td></td>
<td>• Facilitate professional development.</td>
</tr>
<tr>
<td>Regulatory interventions</td>
<td>• Create the conditions for rural health workers to do more.</td>
</tr>
<tr>
<td></td>
<td>• Train personnel to meet rural needs.</td>
</tr>
<tr>
<td></td>
<td>• Make the most of compulsory service.</td>
</tr>
<tr>
<td></td>
<td>• Tie education subsidies to mandatory placements in rural areas.</td>
</tr>
<tr>
<td>Financial incentives</td>
<td>• Make it worthwhile to move to a remote or rural area.</td>
</tr>
<tr>
<td></td>
<td>• Provide additional financial benefits.</td>
</tr>
<tr>
<td>Personal and professional support</td>
<td>• Pay attention to living conditions.</td>
</tr>
<tr>
<td></td>
<td>• Ensure that the work-place is of an acceptable standard.</td>
</tr>
<tr>
<td></td>
<td>• Foster interaction between urban and rural personnel.</td>
</tr>
<tr>
<td></td>
<td>• Design career ladders for rural personnel.</td>
</tr>
<tr>
<td></td>
<td>• Facilitate knowledge exchange.</td>
</tr>
<tr>
<td></td>
<td>• Raise the profile of rural personnel.</td>
</tr>
</tbody>
</table>

Source: adapted from reference (44)

3J Professional regulation

As for other health services, professionals working in prosthetics and orthotics services should be regulated to protect users from harm. Prosthetics and orthotics clinicians can be regulated as part of the regulation of other health and allied health professionals by an independent State body, which creates a register of practising professionals. The regulators may publish an accessible list of registrants, so that users and employers can verify the status of prosthetics and orthotics clinicians. Regulators expect registrants to uphold the highest attainable standards of training, professional skills, codes of conduct and ethics. The registration authority should remove individuals from the register if significant misconduct is found, in order to reduce the risk of users.

Prosthetics and orthotics technicians and other technical personnel should be supervised by a regulated or certified prosthetics and orthotics clinician, who assumes responsibility for their conduct.
3K Professional recognition

Lack of recognition of prosthetics and orthotics personnel can negatively affect their motivation, retention and professional development, which may limit service development, particularly in many low- and middle-income countries. Awareness-raising about the nature and role of these professions is necessary to strengthen recognition (see 1Q). Recognition is also related to factors such as salary levels, status, profile, protected title, career development possibilities, certification and registration.

Two aspects of professional recognition should be strengthened:

- recognition that prosthetists and orthotists, associates and technicians have distinct professional titles and job roles in health care provision; and
- recognition of prosthetics and orthotics professions in local career structures, with employment conditions aligned with those of other health care professionals, associates and technical personnel.

3L Professional associations and societies

Professionals working in prosthetics and orthotics are encouraged to be members of and actively participate in the professional body of their discipline to raise awareness of the profession. Prosthetics and orthotics clinicians and nonclinicians are encouraged to form their own professional associations or societies and link them to regional and international federations and societies.

Professional bodies should support and promote evidence-based practice and develop a national ethical code of conduct. They may further the development of their profession by sharing best practice in publications, networks, events and refresher training for their members. Professional bodies may also engage and advise regulators about their codes of practice, participate in national planning and promote their professional fields.

Professional societies and associations can also be formed around a topic, health condition or field of knowledge to bring together an interdisciplinary group of personnel and stakeholders to share information about treatment of that condition. Such organizations should allow both professional and user membership.
4A User policy

To ensure that prosthetics and orthotics services are user-centred (see Box 13), service providers should have a written user policy in the local language describing how users and caregivers should be treated throughout their contact with the service and how their rights will be upheld. All personnel should be adequately trained in the user policy, and service providers should be able to present evidence of compliance with the policy.

Box 13. Features of user-centred prosthetics and orthotics services

User-centred prosthetics and orthotics services are planned from the perspective of the users and respond to their needs, choices and preferences in humane, holistic ways. As a minimum they have the following features:

User-friendly environment: Service units should be fully accessible and provide a user-friendly environment. Waiting areas should be clean, quiet and comfortable, with a pleasant temperature, fresh air, sufficient seating even at peak hours and a television or magazines and play options for children, to make waiting easier and more comfortable.

Respect: The provider–user relationship should be built on dignity, empathy, mutual respect, honesty and trust, making sure that the values, needs and wishes of users are taken into account. Personnel should have a polite, professional attitude and should communicate effectively and listen attentively to users. The clothing of the personnel should respect the local culture.

Punctuality: Services should be prompt, without unnecessary delays, respecting scheduled appointment times.

Safety: The safety of users must be ensured in all phases of treatment and in all areas of the service unit. Safety measures must be in place to protect users against injury (during treatment, during training with prostheses and orthoses and whenever tools and machines are used), health hazards (including infections and exposure to potentially dangerous chemicals used in treatment or production) and verbal and physical violence or abuse.

(Continued over)
The user: a central resource in planning and provision of services

Service users must not be regarded merely as recipients of prosthetics and orthotics services but as partners, who can contribute to improving and sustaining services both locally and nationally. Users and their families and caregivers are individuals who have knowledge that is critical to making sure that services are of high quality and well adapted to their needs. They are, in their own right, experts in prosthetics and orthotics.

Users should, through their representatives (user groups and disabled people’s organizations), be involved in the planning, implementation, monitoring and evaluation of prosthetics and orthotics services, at all levels. Their representatives should be on relevant decision-making committees, including national prosthetics and orthotics committees or similar entities (see 1A, Box 1) and advisory committees of service units (see 4Q, Box 31).

User groups may also be involved in collecting user feedback (see 4R) for quality assurance of service providers. Feedback is likely to be more sincere and unbiased when collected by
peers rather than by representatives of the service provider, as users depend on the services for further assistance. User groups may also be important in referral, peer support (see 4P, Box 28) and impact assessments (see 1P).

4C The right of users to choose their service provider and technology

Service users have the right to follow their individual preferences in making the final choice of which service provider to consult and which prosthetic and orthotic technology to accept. The right to choose a provider promotes healthy competition, which can improve the quality and cost-effectiveness of services and make them more affordable.

The right to choose a provider

Users should have the option to choose their provider, if there is no extra cost that is not covered by either the usual financing system or the users. In order that they can make an informed decision, those referring them should give them complete information about their options, including the providers who have the appropriate expertise for the user’s needs, how the services can be accessed and whether service fees apply or are covered by health and social insurance.

The right to choose technology and brand

Service users should be given the opportunity to choose the types of components, materials and design of their prosthesis or orthosis from the options available in the country and within the limits set for financing or reimbursement, if the technology is consistent with the user’s needs. Member States should ensure the availability of several technologies to suit different needs and pockets.

The choice of components and materials must not be the monopoly of any one supplier or service provider. In many countries, component manufacturers are also service providers. In these situations, to respect users’ rights and free competition, providers must offer a range of products in addition to their own. All applicants for licensing should disclose any conflict of interest (see Licensing of services in 1B).

4D Accessible services

Service providers and national stakeholders should ensure equal access for all people in need, irrespective of disability, health condition or socioeconomic status. Services must be financially, physically, geographically, socially, linguistically and organizationally accessible.

Financial access: All people in need should be able to obtain the prosthetics and orthotics services they require without suffering financial hardship (see 1J). The costs of the product and service delivery should be affordable for all, including poor and vulnerable people.
Physical access: Service units should be designed so that people with restricted mobility (many of whom use wheelchairs or crutches) can readily access all parts of the premises accessible to users, including the waiting room, treatment sections and toilets. Ramps or lifts should be installed where steps and stairs constitute physical barriers. Service units should have ample parking space dedicated for their users.

Geographical access: Services should be available to all users, wherever they live. In most countries, this will require establishing a network of service units appropriately distributed throughout the country (see 4G) or decentralization of services (see 4H). Service users and caregivers may also require financial support for travel to and accommodation at the service location (see 1M).

Social access: Services should be offered in the same way to all people, irrespective of their gender, age (with the possible exception of services specifically for children and for the elderly), social background, ethnicity, cultural values, religion, beliefs, sexual orientation or refugee or migrant status.

Linguistic access: Service users should be able to communicate with the service provider in their own language or dialect. All information materials should be available in the local language and in an accessible format. Sign language interpreters should be available for people with speech impairments.

Organizational access: Opening hours, waiting times and appointment systems should suit all users, including those coming from remote locations and those who work during the day.

4E Types of service provider

Prosthetics and orthotics services can be provided by public, private (for profit or not-for-profit) and nongovernmental and philanthropic organizations. Most countries will require a combination of different service providers to ensure equitable access to affordable, high-quality services for all. The advantages may be several sources of funding and a wider reach of services.

Public service providers

Governments must ensure that high-quality prosthetics and orthotics services are available at an affordable cost for everyone, everywhere. States can fulfil this responsibility in various ways, including establishing service units at different levels and providing the services directly. This may be the case in countries where prosthetics and orthotics service coverage has not yet been included in national health and social insurance schemes. Public service provision is often characterized by a long-term commitment.

Public prosthetics and orthotics services may be provided by the ministry of health and also by ministries for social welfare, education and defence, the last usually being limited
to military personnel and war veterans. Occasionally, services may be provided by more than one ministry; this requires close intersectoral collaboration to minimize duplication and waste of resources. In some countries, funds are provided by one ministry and services delivered by another.

**Private for-profit service providers**

In many countries, prosthetics and orthotics services are provided by private enterprises or commercial establishments. The advantage is that market competition can stimulate the provision of more cost-effective services, reduce costs and increase quality; however, as few users are likely to be able to pay the full cost of prosthetics and orthotics treatments and products, private services will be viable only if the costs are subsidized by the State or covered by insurance or welfare schemes. Otherwise, the private sector will cater only for people who can afford their prices. To ensure safety, quality and accountability, the private service must follow State regulations (see Regulation in 1B).

**Private not-for-profit service providers**

A private not-for-profit entity or social enterprise is run in most aspects like a commercial company, with many of its advantages. While a private company’s purpose is usually to make a profit, however, that of a social enterprise is to maximize improvements in well-being. The profits are reinvested in services for the benefit of poor users (cross-subsidization) instead of being paid to the owners or shareholders of the company. As in a private company, a social enterprise depends on subsidies and insurance coverage, and services must follow State regulations.

**Nongovernmental and philanthropic organizations**

In some countries, prosthetics and orthotics services may be provided by not-for-profit NGOs, such as charities and faith-based organizations. This is more frequent in low-income settings, where services are often started by NGOs in response to a highly apparent need that has not been met by public or private services.

NGO services have a social approach similar to that of social enterprises, but services are often provided free of charge or at a subsidized rate. (For concerns with regard to free services, see 1L.) NGO services often rely on private donations and funds from philanthropies or corporate social responsibility initiatives but may also be financed by the government or insurance funds. Services are often provided within a project, which may place them at risk for funding cuts. Like other entities, NGOs must comply with State regulations.

**4F Inclusion of prosthetics and orthotics services in the health sector**

Prosthetics and orthotics services are best positioned within the health ministry and integrated and mainstreamed into the national health care system. The benefits include the fact that these specialized health services provide interventions for a range of health conditions, contributing to better health outcomes and furthering universal health coverage.
Prosthetics and orthotics treatments are usually provided in conjunction and collaboration with other health services such as surgery and rehabilitation, and close linkage is critical for the outcomes (see Box 14); these treatments can also reduce health costs (see 1F).

Box 14. Mutual benefits of including prosthetics and orthotics services in the health sector

Many prosthetics and orthotics service users require medical treatment, wound healing, X-ray, surgery, therapy and other interventions during treatment. The entry point of prosthetics and orthotics services is often general health services. For example, a prosthetic fitting is required after amputation, an orthosis after surgery or paralysis, and diabetic conditions often require special footwear. Many prosthetics and orthotics service users are hospital inpatients or have just been discharged. Prosthetics and orthotics service providers, irrespective of their affiliation, should therefore work with hospital departments, including orthopaedics, rehabilitation, diabetes, neurology, paediatrics, geriatrics and emergency. When the prosthetics and orthotics services are not in the same building or campus, providers can maintain contacts by holding consultations within hospitals and clinics.

Collaboration between prosthetics and orthotics services and decentralized health services is of particular importance, as district hospitals and PHC and community health programmes can identify, refer and follow up users. As part of the health sector, prosthetics and orthotics services can make use of established networks to reach people in need everywhere in the country. This also benefits the health services, as it can strengthen the continuum of care and increase the range of services available. Such collaboration can ensure that health conditions requiring prosthetics and orthotics treatment are identified and treated at an early stage (see 1H).

The inclusion of prosthetics and orthotics services in the health sector contributes to the provision of inclusive health services for all, including people with disabilities. It also reinforces the continuum of care, from preventive, promotive, curative, rehabilitative, assistive interventions to palliative care.

While the ministry of health is usually the lead ministry for prosthetics and orthotics services, others may make important contributions, by direct service delivery, by their part in the rehabilitation continuum and in areas such as education, economic empowerment and social integration. In particular, there should be strong links between health, education, employment and social sectors.

4G Service delivery systems

The distribution of prosthetics and orthotics services should match overall need and the population distribution in the country. Most countries will require several service units (see Box 15) of different capacity, at different levels and in various geographical areas.

Ideally, all service units should provide the full range of services. In many contexts and particularly in poorer settings, however, this may not be practically or financially possible, as it would require comprehensive service units and specialized personnel for treating rare and complex cases at all locations. Responsibilities can be distributed to different service
levels with slightly different tasks. Together, the system will provide all the types of service needed, with the expectation that the widest possible range of services is offered as close as possible to potential users.

**Box 15. Numbers of prosthetics and orthotics service units required**

The number of service units required to cover the needs for prosthetics and orthotics in a country depends on the geographical setting, the types of service provided in each unit and their size and location. This varies widely by country.

On average, a country will require one to three prosthetics and orthotics service units per 1 million population, on the assumption that each unit can assist 1500–2000 users per year (covering all types of intervention). More precise figures from national and international studies and research should be made available to determine the precise numbers of units required in different countries.

**The three-level prosthetics and orthotics service delivery system**

Like the three-level health care system and preferably integrated within it, a system of primary, secondary and tertiary services can be used to organize prosthetics and orthotics services (Fig. 3).

**Fig. 3. Three-level delivery system for prosthetics and orthotics services; exclusive and inclusive approaches**

At **primary level**, to ensure that the widest range of services can be provided as close as possible to the users, services can be extended from the exclusive prosthetics and orthotics approach to an integrated approach involving other health and rehabilitation sectors in identification, referral and follow-up and in the provision of a limited range of very basic prosthetics and orthotics treatments, as decided by the tertiary and secondary services (the inclusive health system approach).

At **secondary level**, standard prosthetics and orthotics units provide a range of the most commonly required treatments for people in provinces and districts, including those referred
from primary level. These units, preferably integrated into hospitals, should have established links and standardized referral pathways to tertiary level services for rare conditions, complex cases, advice and second opinions.

At tertiary level, specialized services are provided by, for example, national or regional centres with the full range of specialist prosthetics and orthotics services or by specialist clinics designated to provide comprehensive, multidisciplinary treatment for rare and complex conditions, such as congenital limb deficiency, antenatal care and complex amputation surgery and prosthetic fitting. Tertiary level centres are expected to be centres of excellence that provide national or regional leadership, best practices, research, support and/or training in particular areas. They should be able to offer a wide range of technology to meet specific needs and should have access to inpatient rehabilitation beds for complex cases.

After treatment at secondary and/or tertiary levels, users can be followed up at primary level, as close as possible to their homes.

Technical support and monitoring should be provided throughout the system to ensure that high quality is maintained at all levels and in all types of service. Particular attention must be paid to quality at primary level where personnel have less specialized training.

In large countries, there may be more than one service unit for specialized services at the tertiary level, and some countries may also have standard prosthetics and orthotics units at the primary level (see Box 16).

Box 16. A decentralized prosthetics and orthotics service delivery system in China

Access to prosthetics and orthotics services can be improved by decentralized provision through a close-knit network of service units. An estimated 24 million people in China experience physical disability (45). Of these, 2.3 million are amputees who need prostheses or other mobility aids; others have physical impairments, most of whom require orthoses, wheelchairs and other mobility aids. To address this huge need, the China Disabled Persons’ Federation established a nationwide network of permanent prosthetics and orthotics service units at all levels. Currently, the Federation has 180 service units in the provinces and cities and nearly 1000 units of different scales and sizes in counties. These units, with mobile and outreach service facilities, go towards ensuring that prosthetics and orthotics services are available in most parts of the country. Within the Cheung Kong New Milestone programme, a longstanding collaboration between the China Disabled Persons’ Federation and the Li Ka-shing Foundation, China continuously upgrades and strengthens the capacity of the decentralized prosthetics and orthotics service system.

Systems of private prosthetics and orthotics service providers

In countries where citizens are effectively covered by public or private insurance, the advantage of private prosthetics and orthotics services is that they tend to be distributed according to the demand for services and correspondingly have a financial incentive to provide services. A private actor will be interested in establishing a prosthetics and orthotics
unit of the appropriate size and with suitable specialization in a country in which there is a favourable environment for private business.

Private services may be provided by stand-alone units or, more typically, by enterprises that have branches in various cities and largely function as separate service systems. While collaboration with other service providers (which would be seen as competitors) may be limited, there is a strong financial incentive for private service providers to collaborate with the health sector, which can increase both client numbers and income.

**4h Decentralization of services**

Although it would be financially impossible to have complete prosthetics and orthotics service units in all cities and communities in a country, the services must be made accessible for people in remote and rural areas. A service unit can serve as a hub for the provision of decentralized services through, for example, satellite units, mobile units, outreach services or liaison with community programmes and outreach campaigns. Each of these approaches has its advantages and disadvantages (Table 4). All depend on services and support from a prosthetics and orthotics unit, and most face challenges in assuring the quality of treatments and products. Decentralized services must therefore be monitored closely and the results carefully followed up and evaluated.
Table 4. Advantages and disadvantages of different means of providing decentralized prosthetics and orthotics services

<table>
<thead>
<tr>
<th>Means of decentralization</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satellite services</td>
<td>• Can provide the same range of services as the main service unit</td>
<td>• The degree of decentralization is more limited than that of outreach and mobile services but can be increased by establishment of several units.</td>
</tr>
<tr>
<td></td>
<td>• Can maintain the same quality standards as the main service unit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can be integrated into a health facility and stimulate collaboration with the health sector</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can become a permanently staffed service unit</td>
<td></td>
</tr>
<tr>
<td>Mobile services</td>
<td>• Can reach the least centralized parts of a country</td>
<td>• Complicated cases and those requiring long training must be referred to a main service unit.</td>
</tr>
<tr>
<td></td>
<td>• Are less dependent than outreach services on the main service unit and can be operational for longer</td>
<td>• The range of treatments and products that can be provided without compromising quality may be limited.</td>
</tr>
<tr>
<td></td>
<td>• Can be efficient and assist a large number of users</td>
<td>• Cost–effectiveness may be low.</td>
</tr>
<tr>
<td></td>
<td>• Can play an important role in identification and referral of potential users</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can assure a broad range of repair and maintenance work</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can raise awareness about disability issues, prosthetics and orthotics needs and the role and benefits of the services</td>
<td></td>
</tr>
<tr>
<td>Outreach services</td>
<td>• Can reach the least centralized parts of a country</td>
<td>• Depend on the main service unit for fabrication of all custom-made products</td>
</tr>
<tr>
<td></td>
<td>• Can identify and refer potential users</td>
<td>• Insufficient time for the treatment of most users, who must be referred to a service unit</td>
</tr>
<tr>
<td></td>
<td>• Can assist some users</td>
<td>• High risk that the quality of treatment is below acceptable levels</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Only a limited range of treatments and products can be provided.</td>
</tr>
<tr>
<td>Linkage with CBR and other community programmes</td>
<td>• Facilitates early identification and intervention</td>
<td>• A very limited range of treatments can be provided; the vast majority of users have to travel to the service unit.</td>
</tr>
<tr>
<td></td>
<td>• Can refer potential users and follow them up after treatment</td>
<td>• The quality of treatments may be poor.</td>
</tr>
<tr>
<td></td>
<td>• Little cost for the prosthetics and orthotics service provider</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• May increase the probability of co-financing services for community members</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can do repairs and maintenance</td>
<td></td>
</tr>
<tr>
<td>Linkage with community outreach campaigns</td>
<td>• Can identify and refer potential users</td>
<td>• Cannot provide prosthetics and orthotics treatment; all users have to be referred to a service unit</td>
</tr>
<tr>
<td></td>
<td>• Little cost for the prosthetics and orthotics service provider</td>
<td></td>
</tr>
</tbody>
</table>
While decentralization of prosthetics and orthotics services usually incurs significant extra costs for the service provider, who must consider the cost-effectiveness of services, it can result in considerable savings for the user and may therefore be economically justifiable (see Box 17). In many countries, decentralization may be the only way of reaching all people in need. People who need more advanced treatment than can be offered in decentralized services can be identified and referred to the right level in the service system.

**Box 17. Decentralization of services: not only a cost but an investment that can generate savings**

The provision of prosthetics and orthotics services involves costs in five categories (see 1E). The two main categories are the cost of the service provider and the expenses of the user (including, for example, the costs of travelling to and from the service location and staying throughout treatment). While decentralization of services increases the costs for the service provider (and donor agencies, the government, insurance systems), users can make large savings and increase their earnings, as they will have to travel less and spend less time away from home or a job.

These aspects must be considered when analysing the overall cost of decentralizing services. Not only is it more practical for users to have the services closer (instead of having large numbers of people travelling to centrally located service units), it may also have economic benefits for society. In addition, decentralized services can ensure better repair and maintenance services, which can increase the lifespan of prostheses and orthoses and reduce the cost of renewals.

**Satellite services**

A satellite service unit is a small facility in a suitable decentralized location, preferably integrated into a hospital or a health centre facility where collaboration can be established with health personnel. The unit may not be permanently staffed initially but visited regularly, perhaps every 2–3 weeks, by personnel from a main service unit. The satellite has the equipment necessary for taking measurements and casts and fitting, repairing and maintaining prostheses and orthoses but relies on the main centre for fabrication.

Starting at a very small scale, a satellite unit can grow and the frequency of visits increase as it becomes better known in the area and the demand for services rises. Eventually, the services may become permanent (see Box 18). At an intermediate stage, the unit may be staffed by a physiotherapist, occupational therapist, nurse or trained CBR worker, who can conduct the first screening and prepare users for treatment, and/or by a prosthetics and orthotics technician, who can make repairs and maintain prostheses, orthoses and other mobility products. To increase decentralization, a main unit may have several satellites. Except for staffing, satellite units should adhere to the same standards as the overall service system.
Box 18. Satellite prosthetics and orthotics service provision in Sweden

The Swedish island of Gotland is located in the Baltic Sea some 100 km off the mainland, a 3-h ferry ride away. With a population of nearly 60 000, it has only recently been provided with permanent prosthetics and orthotics services. Until the 1970s, the only prosthetics and orthotics services offered were those of a shoemaker. In the 1980s, a service provider on the mainland started to make monthly visits to the island’s main hospital, where measurements and casts were taken and prostheses and orthoses fitted and delivered. As the demand grew and visits became more frequent, it was decided in the 1990s to establish a permanent service unit. With two prosthetics and orthotics personnel, this unit is now a provincial centre that can provide a wide range of treatments, and only a few people have to travel to the mainland for specialized services.

Mobile services
A mobile unit is essentially a prosthetics and orthotics service facility on wheels or, in some countries, a boat. It is equipped with the tools and machinery required to produce a certain range of prostheses and orthoses and is staffed by a team ideally including prosthetics and orthotics specialists, doctors, therapists and social and CBR workers. The unit can be used in remote areas, preferably in collaboration with a district or sub-district hospital and PHC centre, to identify needs, directly deliver services, refer users to secondary units, follow-up and carry out maintenance and repair work. It can also raising awareness of prosthetics and orthotics services, which may increase demand and thus favour establishment of permanent service units.

A mobile unit can work independently in a wide area for long periods, up to several weeks or even months, if there are sufficient materials and staff can be compensated for the particular work conditions. This can ensure efficient service delivery.

The provision of mobile services is often more expensive than in a prosthetics and orthotics facility because of vehicle costs and higher personnel costs for allowances and accommodation during field visits. To be cost-effective, a unit should therefore remain at a location for only as long as its capacity is fully used but long enough to ensure that all treatments adhere to standard procedures. These considerations affect the extent to which the needs in a location can be covered. Some cases will have to be referred to a main unit, because they are too complicated or require very lengthy treatment.

Mobile services should not be second-rate services for rural populations but should adhere to the same standards as the main prosthetics and orthotics unit and follow well-defined quality requirements for that type of service. Ensuring the quality of services is more challenging in a mobile unit than at a main unit, and the types of treatments that can be provided are likely to be more limited. On the basis of evaluations of treatment results, the service provider can define the range of treatments that can be provided without compromising quality. Such evaluations must be objective and evidence-based and not based only on users’ opinion, as users in remote areas may not know what they should expect from the services and may have low expectations of fit, function and comfort.
Mobile prosthetics and orthotics services are usually a temporary approach for raising awareness about needs, increasing access to services and paving the way for establishment of a less centralized network of secondary level service units (see Box 19). In some countries, mobile services may be the only way of reaching populations scattered over large areas that are difficult to access (such as deserts, islands and mountainous areas). Mobile services should be considered an important element in the service delivery system and may be critical for providing services to all the people who need them.

**Box 19. Mobile prosthetics and orthotics services in Brazil**

In 2008, the São Paulo State Government in Brazil initiated a network of 20 permanent rehabilitation facilities. While the first service facilities were being built, equipped and staffed, a mobile unit was created to provide decentralized services, build the capacity of local professionals, raise awareness about the right of people with disabilities to access appropriate services and collect data on service needs. The mobile unit was introduced in 2009 and was operational until 2011. It consisted of a 15.4-m long, 2.5-m wide fit-for-purpose tractor–trailer with rooms for waiting, consultation, therapy, fitting, assembly, machine work, plaster work and administrative support. The unit was staffed by a team of prosthetics and orthotics personnel, doctors, physiotherapists, occupational therapists, nurses, administrative officers and a bioengineer. This allowed both assisting users and training local rehabilitation professionals.

The mobile unit provided services in nine of the State’s 17 regional health departments, with three visits in each location. The users were referred from surrounding areas by local health authorities, who also coordinated follow-up. On the first visit, assessments and prescriptions were made and measurements taken, followed by fitting, training and delivery of prostheses and orthoses on subsequent visits. During the three years in which the mobile unit was operational, more than 3300 assistive products were delivered, including lower- and upper-limb orthoses and prostheses, shoes and insoles, canes, crutches and walking frames, benefitting some 1800 users. Increasing numbers have since been assisted at the permanent rehabilitation facilities that were established in some of the regions visited by the mobile unit. The mobile service thereby led the establishment of new services in parts of the State that had previously not been catered for.

Data collected by the mobile unit were used to project the requirements for assistive products in each region and indicated further action, including the establishment of more service units and training of personnel (46).

**Outreach services**

Exceptionally, such as in emergencies or to reach very remote populations, prosthetics and orthotics units can organize outreach services (see Box 20). These services usually consist of a series of visits to a location, preferably organized in collaboration with a district or sub-district hospital or a PHC centre, possibly as part of a health outreach activity.

Outreach services are provided by a team similar to that of a mobile unit (see above) but without most of its tools and machines. Each visit may last one or several days, depending on the size of the targeted population and the distance. On the first visit, potential users are screened, then people who require prosthetics and orthotics are fully assessed and measured, with casts made, or prefabricated devices or mobility assistive products are provided. After the first visit, the team returns to the service unit for fabrication of custom-made products, which are fitted on the second visit. Follow-up visits can be made, or follow-up can be conducted by community workers. Visits may also include a limited range of maintenance
and repair of devices. In some countries, very simple prosthetic and orthotic products might be manufactured at the outreach location.

The challenge of this type of service is guaranteeing the quality of treatment and products, as the service is often provided under considerable time pressure, without access to the full range of equipment and tools required and in an environment that may not readily allow use of standard procedures or ensure the privacy of users. Such services should be provided only when monitoring, evaluation and follow-up of treatment and products verify that they meet the quality requirements. Only a limited range of treatments can be provided in the field, as most users (particularly those who require training and close follow-up) are referred to a service unit.

**Box 20. Outreach prosthetics and orthotics services in Nepal**

Nepal has a population of 27 million, distributed over an area of 150,000 km² in three distinct physiographic areas: the Terai (lowlands), the Hills and the Mountains. Prosthetics and orthotics facilities are located mainly in the lowlands (with the exception of those in the two main cities, Kathmandu and Pokhara), and access to services is difficult for people in vast parts of the Hill and Mountain regions. To ensure rehabilitation of people in these areas, most service providers offer outreach services, potentially reaching all the country’s 75 districts.

Providing outreach services often involves travelling 10–15 hours to reach a district, from which several locations can be visited; usually, 1–2 days are spent at each site. Potential users, who may arrive by foot (or be carried) from places many hours away, are referred by village leaders and personnel in local health, social and education offices and institutions.

The multidisciplinary team of the outreach service makes assessments and provides rehabilitation services on site, where some prefabricated orthoses and mobility aids can be provided. Measurements are taken for some users, who receive custom-built products on a second visit; however, users are referred to the service facility for most treatment. Outreach services significantly increase service use, and screening of potential users ensures that people do not travel to the service unit in vain.

Outreach service providers usually work with community disability workers in the district, who help in organizing visits and are instrumental in following up users and communicating with service facility staff when adjustments, repairs and renewals are needed.

**Linkage with CBR and other community programmes**

In addition to collaborating with PHC services at primary level within the three-level service delivery system (see 4G, Fig. 3), prosthetics and orthotics services can link with community programmes, such as social and CBR programmes (see Box 21), to identify and refer people who require prostheses and orthoses to service units and to follow them up on their return. Developments in information and communications technology can facilitate this work (see Box 22). Some communities may be able to provide funding for users referred to services at secondary and tertiary levels. Basic prosthetics and orthotics treatment may be provided, but only if community workers have received sufficient training and their work is closely supervised. It is important to clearly define what community workers can and cannot do and the circumstances in which they should consult specialists at the prosthetics and orthotics unit.
Box 21. Community-based rehabilitation

CBR can ensure that a large proportion of people with disabilities receive rehabilitation in their communities. CBR workers can identify people with disabilities, conduct basic functional assessments, provide simple rehabilitation treatment, train family members to support and assist a person with a disability, provide information about the types of services available, facilitate referrals to more specialized rehabilitation at secondary and tertiary levels, including prosthetics and orthotics services, and follow up users on their return. CBR programmes can raise awareness in a community about disability, rehabilitation and prosthetics and orthotics services and are important partners of these service providers (47).

Box 22. Telemedicine and telerehabilitation to facilitate prosthetics and orthotics service provision in the Philippines

“Telemedicine”, “telehealth”, “e-health” and “mHealth” are terms used interchangeably to describe clinical services that are provided by use of information and communication technology. Where great distances make face-to-face consultations difficult and expensive, these services can facilitate access to generalists or specialists. They can also be used by health personnel who need specialist advice on rare or complex conditions in order to intervene locally. Images and data can be stored before they are transmitted, or consultations can be made in real time (live streaming).

Telerehabilitation is the application of information and communication technology in the field of rehabilitation services and is used to improve access to services for people with physical impairments or functional limitations, so that more people can be assisted and more specialized interventions and follow-up are available at local level. To be effective, telerehabilitation technology should be “lightweight”, with a simple interface, and should allow real-time communication (48). Lessons learnt from telemedicine and telerehabilitation can be applied to the provision of prosthetics and orthotics services. Areas to be developed include outreach screening, provision of specialist assessment and advice and follow up of users.

In view of the challenge of reaching remote, underserved communities on the many islands of the Philippines, the Department of Rehabilitation Medicine at the Philippine General Hospital initiated a programme, Amputee Screening through Cellphone Networking (ASCENT), in which medical doctors, students and health workers screen amputees in the community. Cell phones are used to record the medical history and transmit the data to a centralized web-based database, with photographs and videos taken with the cell phone camera.

ASCENT has created a registry of amputees, provided a tool for screening the parameters of prosthesis use, identifies amputees at risk of a second amputation and enhances the role of the rehabilitation team. The registry provided the data necessary for creation and implementation of the Philippine Health Insurance Commission Prostheses Benefit Package. ASCENT overcomes many challenges by making evaluation paperless and user-friendly and facilitating access to prosthetics services in rural and geographically remote areas.

Linkage with community outreach campaigns

Governments and NGOs sometimes provide direct support to communities in, for example, vaccination campaigns, HIV/AIDS awareness-raising projects, registration of voters and literacy campaigns. These outreach interventions, even though they are temporary, offer opportunities for raising awareness about prosthetics and orthotics and identifying and referring people who need such treatment. Prosthetics and orthotics service providers can link with such initiatives in order to increase service coverage.
Maintenance and repair services

For prostheses and orthoses to remain useful, they require regular maintenance and occasional repairs. Sometimes, adjustments are required to ensure that the products remain comfortable and functional. An amputation stump, for example, may gradually become smaller as a natural result of atrophying muscles, or it might become larger due to oedema or weight gain; this will affect the fit of the prosthesis. Similar changes can influence the fit, comfort and function of orthoses. Adjustments, maintenance and repair, although often small, can ensure that prostheses and orthoses have a long lifespan; they are critical for the users’ comfort and to maintain their confidence in the services. Maintenance and repair may also save costs for users, service providers and society.

Maintenance and repair services should be an integral part of a prosthetics and orthotics service system and should be provided as close as possible to users, by the service unit itself and through decentralized services (see 4H). They can also be provided by dedicated, decentralized maintenance and repair facilities, perhaps providing similar services for mobility and assistive products in general. This may involve working with others in wider fields, such as CBR workers. In all cases, concerned individuals should be trained. The range of maintenance and repairs that can be done by workers with no formal prosthetics and orthotics training should be carefully defined. The repairs are likely to include minor (but, for the user, important) interventions, such as replacing straps and providing spare socks.

Service provision in disasters

Prosthetics and orthotics services are often needed after natural and manmade disasters, such as earthquakes and civil conflict, with increasing numbers of people with acquired impairments such as spinal cord injury, traumatic brain injury, limb amputation, fracture, peripheral nerve injury and crush injury (49,50). Some of these victims will require immediate prosthetics and orthotics treatment. Often, the local services for assisting these victims are also affected by the disaster, and international support may be required to rebuild and strengthen them.

International support often involves establishing clusters for coordinating and channelling work to different sectors. Prosthetics and orthotics are usually part of the health sector response and are coordinated by a health cluster, preferably in a sub-cluster for rehabilitation. Governments should be encouraged to play a leading role in coordination. If there is a national prosthetics and orthotics committee or similar (see 1A, Box 1), it is usually well placed to assume coordination and planning, with the involvement and support of relevant international actors. Coordination is critical from an early stage to ensure that all national and international stakeholders work towards a common goal, which should correspond to the national long-term goals. International support projects must conform to national strategies, such as for use of technology and training of personnel, so that services can be sustained by national stakeholders when the support ends.
In disasters, it is particularly important to protect vulnerable groups such as people with disabilities (especially children and women). Their rights, as outlined in the CRPD, must be respected, including ensuring access to rehabilitation services. The aftermath of a disaster may highlight rehabilitation needs and provide an opportunity to raise disability issues on the national agenda.

Support for victims of a disaster who need prostheses and orthoses involves the actions shown in Fig. 4.

**Fig. 4. Phases of the prosthetics and orthotics rehabilitation continuum in disaster contexts**

### Emergency phase
- Triage
- Provision of a limited range of mobility devices
- Advice to health and rehabilitation personnel
- Data collection
- Planning

### Reconstruction phase
- Prosthetics and orthotics service delivery
- Follow-up
- Long-term planning
- Policy development

### Long term
- Capacity-building
- Systems strengthening
- Training of personnel
- Strengthening of service units

Source: adapted from reference (49)

**Emergency phase**
Prostheses and orthoses do not usually save lives, but services must be planned in the immediate emergency phase without delay. Information should be collected on the number of victims who need prosthetics and orthotics treatment, the capacity of local services, the personnel available and the technical and material support that may be required to restore and strengthen existing services to provide sufficient assistance.

In the emergency phase, victims might need some orthoses (such as off-the-shelf products to stabilize limbs and spinal fractures) and mobility products (such as wheelchairs and crutches) to prevent secondary impairment and to facilitate mobility. Prosthetics and orthotics specialists should work with surgeons, therapists and other health personnel in assessing victims and give advice on, for example, amputation levels, prosthetic considerations, type of baseline data to be collected, referral processes and prevention of secondary impairment (49-51). Planning of subsequent service delivery should start in parallel to ensure that the materials and working methods are compatible with those to be used in the long term.
Reconstruction phase
Fitting of prostheses and orthoses should start as soon as the healing of injuries and the security situation allow. It will be increasingly difficult to achieve good rehabilitation outcomes if services are not provided promptly. New service units might have to be set up to complement or replace inoperational services. All activities should be conducted with a view to the long term.

Long-term provision
Service users who are assisted during the reconstruction phase must have ensured access to reliable long-term services, as should all people who need prostheses and orthoses. The provision of long-term, sustainable services may require strengthening the capacity of service units and investing in training of personnel. This must be considered in planning and budgeting international support.

Disaster preparedness
Countries that are particularly prone to disasters can make preparations to ensure that prosthetics and orthotics treatment can be provided with other rehabilitation services at an early stage. They might set up stocks of essential orthoses and mobility devices and add prosthetics and orthotics to the disaster preparedness training of health personnel and community workers.

Exclusive and inclusive service units
A prosthetics and orthotics service unit may be an exclusive, stand-alone entity or it may be an integrated part of a health, rehabilitation or assistive products provision facility. Prosthetics and orthotics services that are integrated into the national health care system (see 4F) are usually in hospitals and rehabilitation facilities. Exceptionally, these units may specialize in only one discipline – prosthetics or orthotics – or even in one subfield, such as spinal orthoses.

Exclusive service units
An exclusive, stand-alone prosthetics and orthotics unit is not part of a larger service facility. It may still be part of a wider network of service providers, such as one of several units of a ministry or a commercial company. The advantage of an exclusive unit is that it is more flexible in terms of location, making it easier for users to access. Exclusive units may, however, have more difficulty in establishing direct links with hospitals and other rehabilitation services; and many users may find it inconvenient and expensive to attend multiple appointments for different health needs at different locations.

Inclusive service units
Prosthetics and orthotics units are frequently integrated into larger health service facilities, which may be advantageous for both the service unit and the larger facility, as direct contact between prosthetics and orthotics personnel and other health personnel can facilitate inter-referral and generally improve the results of health and rehabilitation services (see 4F). Any type of prosthetics and orthotics service provider – public, private or NGO – can be integrated
into a larger health structure; the integrated service unit is not necessarily part of the same organization as the larger facility. Private prosthetics and orthotics units, for example, are often integrated into public hospitals.

**Integrated services for mobility and assistive products**

Prosthetics and orthotics services may be part of a facility that provides mobility products, including crutches, walking frames, wheelchairs and special seating (see Box 23), or of a facility for even broader assistive technology, including vision and hearing aids. This may be an approach for establishing decentralized maintenance and repair services. As certain staff skills, equipment, tools and service systems are common to the different fields, services may become more economical when resources are shared.

**Box 23. An inclusive approach to provision of assistive products in Samoa**

Combining different assistive technologies in one service unit is an effective way to improve access to these technologies, including prostheses and orthoses. Samoa Integrated Mobility Device Services is a collaboration between the Samoa National Health Service, Nuanua O Le Alofa, and Motivation Australia, to ensure consistent, reliable, equitable, sustainable access to appropriate mobility devices. A new facility has been built, which is staffed by trained personnel who are working towards new careers in allied health services for Samoans. Services for wheelchairs, supportive seating, prostheses, orthoses and walking aids are combined into one mobility device department.

**Segregated services**

Very exceptionally, service units that target a well-defined group of users (such as children with amputations or neurological disorders and people with spinal impairments) provide services in only prosthetics or orthotics. While this may be justified in some cases, it is more practical and cost-effective to provide both services in one place. The tools, machines, equipment and raw materials used are similar, and the professionals have similar training, so that savings can be made on investment and running costs.

**4L The service unit**

Prosthetics and orthotics services are provided in facilities that are designed and adapted for people who need these devices. A typical service unit consists of four areas: a reception and waiting area, a clinical area, a workshop and rooms for administration (see Box 24). The layout and size of the unit should be suitable for the intended workload and the types of services to be provided. For example, if prostheses and orthoses are fabricated at a central facility shared by several units, only a small workshop area will be required in the service unit.

Users should have direct, easy access to the reception and waiting area and relevant clinical areas. All user areas, including toilets, should be physically accessible and ergonomically designed. Waiting rooms and clinical areas should be separated from the workshop to minimize the risk for injury and exposure to loud noise, dust and the fumes of (potentially
harmful) chemicals used in the manufacture of prostheses and orthoses. User areas should be friendly and have a clinical appearance (see 4A, Box 13, and 1R). As required in the local context, the possibility of treating girls, boys, women and men separately should be offered.

Box 24. The four main areas of a prosthetics and orthotics service unit

<table>
<thead>
<tr>
<th>Service user areas</th>
<th>Staff areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reception/waiting area</td>
<td>1</td>
</tr>
<tr>
<td>- Waiting room</td>
<td>2</td>
</tr>
<tr>
<td>- Reception</td>
<td>- Assembly room(s), laboratory(s)</td>
</tr>
<tr>
<td>- Toilets</td>
<td>- Plaster modification room</td>
</tr>
<tr>
<td>Clinical area</td>
<td>- Plastic room</td>
</tr>
<tr>
<td>- Assessment room</td>
<td>- Machine room</td>
</tr>
<tr>
<td>- Casting/measuring</td>
<td>- Store</td>
</tr>
<tr>
<td>room</td>
<td>- In larger service</td>
</tr>
<tr>
<td>- Fitting room</td>
<td>units, facilities for</td>
</tr>
<tr>
<td>- Gait training area</td>
<td>a wider range of</td>
</tr>
<tr>
<td>- Physiotherapy</td>
<td>services may be</td>
</tr>
<tr>
<td>- Shower room</td>
<td>available.</td>
</tr>
</tbody>
</table>

In larger service units, facilities for a wider range of services may be available.

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**4M Equipment**

The equipment usually used in a service unit comprises general craftsman’s tools and more specific tools for the fabrication of prostheses and orthoses (see examples in Box 25). The numbers and sets of equipment depend on the size of the unit and the types of service provided. The choice of equipment has a direct bearing on the cost-effectiveness of services. The market should be searched for the most appropriate tools, machines and other equipment, with a careful comparison of prices, quality and availability. Investing in good-quality equipment, even if it is initially more expensive, can reduce maintenance and replacement costs, making the prostheses and orthoses more affordable in the long term. All items should be maintained regularly according to the recommendations of the supplier or manufacturer, and there should be a plan for machine replacement.

As for prosthetic and orthotic components and materials (see 2F), national stakeholders should work with relevant authorities and ministries to ensure that tools, machines and other equipment used exclusively for the fabrication of prostheses and orthoses are exempt from import taxes and customs fees.

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**Box 25. Examples of equipment used in a prosthetics and orthotics service unit**

<table>
<thead>
<tr>
<th>Section</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment room</td>
<td>Record-keeping tools; tools and equipment for assessing users</td>
</tr>
<tr>
<td>Casting and measuring room</td>
<td>Shape capture equipment; measurement tools</td>
</tr>
<tr>
<td>Plaster modification room</td>
<td>Mould modification tools and equipment</td>
</tr>
<tr>
<td>Plastic room</td>
<td>Equipment for thermoplastic forming and/or laminating (e.g. oven, vacuum machine)</td>
</tr>
<tr>
<td>Assembly room</td>
<td>Hand tools, drilling machine, sewing machine, etc.</td>
</tr>
<tr>
<td>Machine room</td>
<td>Socket router, heavy-duty drill, etc.</td>
</tr>
<tr>
<td>Therapy and gait training</td>
<td>Therapy equipment, parallel bars, mirrors, etc.</td>
</tr>
</tbody>
</table>

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**4N Working environment and safety**

The provision of prosthetics and orthotics is clinical work, done in an environment similar to that of a medical facility, but certain technical tasks are performed in a workshop. Some of the tools and machines used are noisy, produce dust and may cause physical injury; frequently, the chemicals used are hazardous to the skin and lungs. To protect the safety and health of both users and personnel, prosthetics and orthotics service units should have documented safety rules, with visible health and safety notices explaining the rules and the potential dangers in each section of the unit. Fire extinguishers, first aid kits and eyewash stations should be easily accessible, and smoking should not be allowed. Personnel should receive adequate training in the rules and procedures in the case of accidents, fire or another
emergency. All personnel must adhere to the rules. In the event of an accident, users and personnel should be covered by relevant insurance policies.

In the workshop area, workers’ health and safety should be protected by ensuring, for example, that:

- protective gear, such as gloves, masks, goggles and ear protection, are used for hazardous work (as defined by safety rules);
- effective systems are in place to exhaust dust and fumes from workshop areas;
- noisy machines are used only in dedicated, preferably sound-isolated rooms;
- machines are correctly installed, with ample space around them and according to the instructions of the supplier or manufacturer, so they can be used without risk of accidents;
- tools and machines are regularly maintained and in good order; and
- all technical personnel are trained in the safe use of tools, machines and materials.

**Monitoring safety**
Safety should be monitored by collecting and analysing data on adverse incidents in service delivery, including data on accidents, near-accidents, injuries, infections, irregularities, misbehaviour of personnel or other faults that might jeopardize the safety of users and personnel or have negative implications for the service. Such events should be carefully followed up and recurrence prevented. Protocols should be in place to minimize adverse incidents. User feedback should be encouraged to ensure that all incidents are recorded.

**40 User identification and referral**

Identification and referral of users is important to ensure that those who need services can be directed to a unit where the services can be delivered (see 4P).

**Identification of need**
A person’s need for prosthetics or orthotics service is often identified in the health sector, for example when the person seeks assistance at a hospital or clinic for a chronic condition or impairment-related problem, or as the immediate result of a medical intervention, such as amputation. Often, however, people who need prosthetics or orthotics services are unaware of the availability and benefits of these services. This is likely to be a problem, particularly in poorer settings, where health services may be less developed, few professionals are trained to identify needs and less is known about referral possibilities. In such settings, people are commonly referred to prosthetics and orthotics services by peers and user groups.

To ensure that people in need are referred to the appropriate services, personnel in the health and social sectors should be made aware of the availability of the services and how to access them as part of usual awareness-raising activities (see 1Q), possibly in combination with targeted training in identification.
Referral

The precise rules and customs for referral to a prosthetics and orthotics service depend on the country and local service and financing systems. Referral processes should be established and included in service policies at national, local or service unit level, depending on the context. They should include processes for both self-referral and referral by health and other professionals, with the information required for the referral to be acted upon.

In many countries, to benefit from insurance coverage, a user must see a doctor, who makes a first general assessment and prescribes a prosthesis or orthosis. The doctor should be specialized in physical and rehabilitation medicine or orthopaedics, with adequate knowledge of prosthetics and orthotics and be authorized by the insurance office – public or private – to issue purchase requisitions payable to the service provider.

In many other countries, there is no insurance coverage for prosthetics and orthotics services, and there may be few doctors, especially doctors who are specialized in rehabilitation. Targeted training could be provided to general practitioners or other rehabilitation specialists, who can issue purchase requisitions.

Self-referrals are common in many countries, particularly for the renewal of prostheses and orthoses. Renewals can usually be done with the original purchase requisition, if there is an agreement between the service provider and the paying office on how often and under what circumstances a new product can be provided.

4P The service delivery process

The complete service delivery process is usually done in the service unit, although certain aspects of the services may be delivered outside this. For example, measuring, cast-taking and the trial and delivery of a prosthesis or orthosis may be done at decentralized service locations (see 4H) or when personnel from the unit visit a hospital, and the fabrication of prostheses and orthoses may be done at a centralized location shared by several service units.

Service delivery consists of four steps: (1) assessment, (2) fabrication and fitting, (3) user training and (4) product delivery and follow-up, each of which can be divided into sub-activities (Fig. 5). Many ISO standards that define prosthetics and orthotics terminology, users and methods can be used in formulating and documenting procedures in service delivery (see Box 26).
Once the user is in contact with a prosthetics and orthotics service unit, an appointment is made to assess the individual’s precise needs. Both the user and caregivers should be informed about all the practical issues in the treatment process and the cost implications, if any. If the unit has a large workload and a waiting list, appointments for certain groups of users, such as children, should be prioritized, and guidelines should be in place for prioritization. Appointment systems should allow for emergency situations.

Then, a named prosthetics and orthotics professional should be appointed as the treating clinician and the main contact for the user.

Assessment

Treatment usually starts with a thorough assessment of the user. When required and possible, this is done by a multidisciplinary team of different rehabilitation professionals (see 3C). With a holistic focus and considering the user and caregivers as members of the team, the assessment should define the person’s need by considering body structure and function, activity and participation. The results of the assessment should be shared with the user and caregivers.

Prescription

On the basis of the assessment and after consultation between the multidisciplinary team and the user and caregivers, an informed decision can be made about the most appropriate treatment. Prescribers should check the biomedical and psychosocial goals to be achieved when prescribing a prosthetic or orthotic product as these influence fit (62). The prescription should specify the design and technical specification of the product to be provided according to the country’s standard classification of prostheses and orthoses (which, in turn should
be based on an ISO standard, see Box 26 and 2E). It should also describe the technology, including components and materials, to be used and any special requirements (such as non-standard designs or components).

**Box 26. ISO standard terminology for prosthetics and orthotics**

ISO Technical Committee 168 on prosthetics and orthotics has prepared standards for:
- the terminology to be used to describe the users of prostheses and orthoses and the devices they use,
- the methods for assessing users and prescribing devices and
- describing the outcomes of treatment.

**ISO standards for prosthetics:**
- ISO 8548 Part 1 specifies a method for describing deficiencies present at birth (33).
- ISO 8549 Part 4 specifies terms relating to limb amputation (52).
- ISO 8548 Parts 2–5 specify methods for describing lower limb amputation stumps, upper limb amputation stumps, the causal conditions for amputation and the clinical condition of people who have had an amputation (35, 53–55).
- ISO 29782 describes factors to be considered in specifying a prosthesis for a person with a lower limb amputation (56).
- ISO 8549 Part 2 specifies terms relating to external limb prostheses and the wearers of these prostheses (34).
- ISO 13405 Parts 1–3 specify a method for classifying and describing prosthetic components (37).
- ISO 29781 specifies factors to be included in describing the physical activity of a person with a lower limb amputation(s) or a deficiency of a lower limb segment(s) present at birth (57).
- ISO 29783 Parts 1 and 2 provide terminology to describe normal gait and prosthetic gait (58, 59).

**ISO standards for orthotics:**
- ISO 8551 specifies terminology for describing people to be treated with an orthosis, the clinical objectives of treatment and the functional requirements of the orthosis (60).
- ISO 8549 Part 3 specifies terms relating to external orthoses (33).
- ISO 13404 specifies a method for categorizing and describing external orthoses and orthotic components (37).
- ISO 29783 Part 3 describes a method for describing pathological gait (excluding prosthetic gait) (61).

Depending on the needs identified in the assessment, the prescription may also include other types of mobility assistive products (see Box 27), preparatory physiotherapy and occupational therapy training, surgery, pain management and psychosocial support.

**Box 27. Combined needs for mobility assistive products**

In their overall care plan, users often need other mobility products, in addition to their prosthesis or orthosis, such as a cane or stick, crutches, a standing frame, a walking frame or a wheelchair. This need may be temporary (during their rehabilitation) or permanent. Many users with degenerative conditions will gradually need additional mobility products to maintain their independence. In the overall treatment plan and prescription of mobility products, care should be taken to ensure that products are combined to the best effect.
Frequently, users and caregivers are directed to appropriate user groups for peer support and counselling (see Box 28).

**Box 28. Peer support and counselling**

Service users benefit from exchanging experiences, knowledge, emotions and thoughts on social or practical issues with people who are in a similar situation or who have gone through a similar experience. In a relationship of equality and peer support, the user can understand how others managed to adjust to their new situation after, for example, trauma or disease. This can give them hope and help them move past the difficulties created in their lives.

Peer support can take different forms, including mentoring, counselling and listening. It can be formal or informal and can be done face-to-face, by telephone or on online forums, in groups or individually. Support can be provided by peers with or without training, by volunteers or by salaried peer counsellors.

All prosthetics and orthotics users should have the opportunity to access peer support, as appropriate to their needs. When relevant, this should also involve families and caregivers. Informal peer support may be offered within normal services, with referral to user groups or organizations experienced in providing such services, as needed. Although peer support is voluntary, it should be encouraged by service providers, as it can increase the user’s motivation, thereby speeding up treatment and contributing to better results overall.

Some assessments lead to a decision not to prescribe a prosthesis or orthosis, for example, if it is deemed that the fitting is not viable or would not benefit the user. The reasons should be fully explained and justified to the user and caregivers and an alternative treatment plan proposed, such as prescription of a wheelchair or therapy. Occasionally, purchase requisitions are inaccurate or inappropriate, and users might have to be referred back to the person who referred them originally.

**Goal-setting**

In collaboration with the user and caregivers, a personalized treatment plan should be prepared and documented, including individual and realistic goal-setting (see Box 29). Short- and long-term goals should be set, regularly reviewed and adapted to the progress made. This may mean modifying the treatment plan.

**Box 29. SMART goals**

Prosthetics and orthotics clinicians, in consultation with the user and caregivers, should set appropriate goals for treatment. Goal-setting should be guided by specific, measurable, achievable, relevant, time-bound (“SMART”) criteria, which, in the context of prosthetics and orthotics treatment, are as follows.

**Specific:** The goals must not be too general but should target well-defined areas for improvement.

**Measurable:** The goals must be measurable, with indicators to quantify and verify improvements.

**Achievable:** The goals must be realistic and attainable, given the potential of the user (as defined in the assessment) and the resources that are available.

**Relevant:** The goals must be relevant to the needs and expectations of the user and caregivers and must be adapted individually.

**Time-bound:** The goals must include target dates and specify the time within which improvements should be achieved.
Fabrication and fitting

Measuring
Fitting of a prosthesis or orthosis usually begins with a set of body segment measurements. For prefabricated products (see 2C), it is usually enough to measure certain lengths and circumferences, which are then used to select a device of appropriate size. (The product may still have to be adapted to the person’s anatomical features; see Fitting and customization below.) When custom-made products are used, measurement often also includes capturing the shape and making a model of the body segment, such as a plaster mould and/or a computer-generated digital picture, which is used in fabricating the device.

Fabrication
Fabrication usually consists of shaping and assembling different components and materials – many of them prefabricated and available in different models and sizes. This may be done while the user is waiting, but a completely customized device usually requires a new appointment.

Prosthetics and orthotics personnel must follow the manufacturers’ instructions and guidelines to ensure full usage of components and to minimize potential risks to users and personnel. Any deviations from standard practice must be fully documented. Manufacturers and suppliers of prosthetic and orthotic components, materials and consumables should inform and train personnel about the best clinical application of their products.

Fitting and customization
Next, the device can be tried on the user and be fully adapted to the body’s anatomical features and movement patterns. Individual customization is required for fit and alignment in order to achieve optimum comfort, function and appearance, thus ensuring that the product can be used effectively. This is done in parallel with user training (see next section). Depending on the type and complexity of the device, customization may be immediate, as is the case with many prefabricated products, or it may require work over several sessions. In some cases, customization may take days or weeks or, exceptionally, even months.

User training

Training
Training of users must be an integral part of prosthetics and orthotics service delivery. Many users have to undergo preparatory training to strengthen their muscles and increase the range of movement in their joints before a prosthesis or orthosis can be fitted. In the fitting process, they should be provided with sufficient functional training to ensure that they become accustomed to the new device, are able to put it on and take it off, can use it effectively and safely and can control its features and functions fully.
Training may be given under the supervision of the prosthetics and orthotics clinician or by a physiotherapist or occupational therapist (see Box 30). Further adjustments can be made to the device, as needed and according to the progress of the user (see Fitting and customization above). Most users require considerably less training when a prosthesis or orthosis is renewed. For users who require regular support in their daily activities, family members and caregivers should be involved in all steps of training.

**Box 30. Therapy interventions in the prosthetics and orthotics service delivery process**

Physiotherapy and occupational therapy interventions are often needed in preparatory training and in the fitting phase (functional training) and are particularly important for users undergoing their first treatment. Physiotherapists and occupational therapists are central members of the multidisciplinary team.

The aim of **preparatory training** is to ensure that individuals are physically ready for the prosthesis or orthosis fitting. The interventions may include strengthening muscles, joints and other structures by direct manipulation or supervised exercises. They may also include massage and, occasionally, electrotherapy and heat treatments.

**Functional training** is begun at the time of the first trials with the prosthesis or orthosis in order to optimize the fit and function. Functional training includes guiding users in moving with the new device, supervising gait training and supporting functional activities to make sure that the individual can use the device in daily life.

Therapy is critical to the overall treatment result and should be an integral part of prosthetics and orthotics service delivery, ideally by including therapists in the service unit. Often, however, they are external resources, either in dedicated physiotherapy and occupational therapy hospital departments or in independent, private entities.

**4 Product delivery and follow-up**

**Product delivery**

Once the fit, function and comfort of the prosthesis or orthosis is deemed optimal and the user is confident in its use, all its features should be checked thoroughly by the responsible prosthetics and orthotics clinician before it is finalized. Users and caregivers should have the final say on the acceptability of fit, function and appearance.

At delivery of the prosthesis or orthosis, the responsible clinician should make a last check of all the essential treatment criteria, by a standard protocol, in consultation with the user and caregivers. If applicable, the results should be reported to the relevant insurance office. The user and caregivers must know how to use and maintain the device (including how to store it when it is not used), when to return to the service provider for follow-up and when and where to go for maintenance and repair (see below). The user is responsible for adhering to these instructions. Users should have an appointment for the first follow-up visit when they leave the service unit. These arrangements should be documented.
Outcome evaluation
At product delivery and in follow-up sessions, the outcome of treatment should be evaluated against the agreed treatment goals with appropriately selected, validated outcome measures, when available. The technical results and direct improvements in the user’s functioning, mobility, dexterity and activity should be evaluated and documented, as well as the impact on participation, such as return to work, education, social inclusion and other aspects of quality of life (see 1P).

Follow-up
After treatment has been finalized, the user must be followed up at certain intervals and the results reviewed. Follow-up should be individualized and should take into account the type of intervention and the age of the user; children should be followed up at least twice a year. Users are followed up to verify that the products are useful and there are no problems with fit, comfort or function and to provide maintenance and repair as required. Follow-up is as important as any other step in the delivery process.

Follow-up appointments also offer an opportunity to collect data for quality assurance and evidence on measures to improve the quality of treatments, products and services (see 4R).

If users miss appointments, service providers should find out why. They have a responsibility to ensure that the devices they provide do not fail the user.

Maintenance and repair
To increase the lifespan of prostheses and orthoses, maintenance and repair services must be provided by the service unit or by collaborating units (see 4I).

Service unit management
A director, manager or management team has the overall responsibility for the operation of the prosthetics and orthotics service unit, while responsibilities for day-to-day activities and supervision should be delegated to appointed heads of section or department (such as administration, finance and manufacturing) and then cascaded to other staff members. Management duties include planning, monitoring, financial work, stock management, material procurement, human resources management, data collection and quality management.

Planning
Planning should be done at unit level but may involve offices at higher levels if the unit is part of a larger organization. Both long-term and annual strategic and operational plans should be in place. Plans should set clear aims (stating, for example, the number of users to be treated and the quality targets to be reached), with benchmarks and performance indicators, so that the results can be readily monitored and evaluated.
Monitoring and evaluation
The activities of a prosthetics and orthotics service unit must be monitored continuously and the results evaluated regularly to ensure that the services are achieving their goals efficiently.

Monitoring is done internally by the unit’s management team (or by offices at higher levels in the organization). Monitoring involves regular collection and analysis of data (including certain service data, see Table 1 in 1O) to make sure that activities are progressing according to plan. A checklist can be used of the goals set for running and developing the services. By comparing service data and other achievements with the checklist, the progress (or delay) in the activities can be determined, and the management can correct any shortcomings.

Evaluation is an objective examination, usually by external specialists (from higher levels in the organization or from outside), of the relevance, effectiveness, efficiency and impact of the unit’s activities and services. The purpose is to identify any deviation from the planned direction, so that it can be corrected and the unit’s work be strengthened. Evaluation complements regular monitoring. It is usually a single event, which may be repeated as needed to ensure that the work is on track. An evaluation may also be a means for reporting to a donor about the outcome of a supported project and for demonstrating that the funds were well managed and spent.

Collaboration
Management of a service unit also includes setting directions for and coordinating collaboration with other stakeholders, such as:

- service user groups;
- health and rehabilitation services;
- social, education and livelihood services;
- CBR programmes;
- disability-inclusive sports and recreation programmes (see 1Q, Box 7);
- local government;
- civil society;
- the business community; and
- donors, investors and insurance agencies.

Although the frequency of collaboration will vary, from day-to-day contact with some partners to annual meetings with others, these contacts are all vital. To be effective, working relations should be formalized, which implies regular meetings and setting common goals and mechanisms for collaboration. To use the knowledge of partners and their advice in planning and running of services further, service units should consider establishing an advisory committee with their membership (see Box 31).
Box 31. Prosthetics and orthotics advisory committee

Prosthetics and orthotics service units can find support in planning, raising resources, monitoring and evaluation by establishing a prosthetics and orthotics advisory committee, with representatives of the most important collaborating partners, which have a direct interest in and can contribute to ensuring well-functioning services. As they may have somewhat different interests in the services, partners can contribute a variety of valuable, complementary suggestions on how the service can be improved, contributing to its general development.

Representatives of users should be members of the committee, giving them opportunities to influence local service design and service delivery (see 4B).

The advisory committee not only safeguards the mission of the programme but also offers opportunities for awareness-raising and promotion of prosthetics and orthotics (see 1Q).

Financial management

A prosthetics and orthotics service provider has various expenses, such as salaries, materials, consumables, rent and telephone and electricity bills. Funds may come from different sources, such as government contributions, insurance payments, donations or user fees (or combinations, see 1K). Good financial management includes planning, procuring, using and controlling the unit’s financial resources to ensure that the services have a solid foundation, can grow gradually and have an important long-term impact. Financial management should be transparent and follow the standard practices of the country.

Stock management and material procurement

A range of components and materials are used in the manufacture of prostheses and orthoses. Service providers should carefully plan the purchase, storage and use of these items so that services are cost-effective, affordable for the user and not interrupted because of a shortage of materials (see 2F). The use of stock management software for procurement and disbursement should be explored.

Human resources management

Prosthetics and orthotics service units should apply and adhere to the staff management procedures used in the public, private or NGO sector of the country. If the unit is large or is part of a wider system of service providers, staff management is usually assured by a specialized human resources department. Typical staff management issues include defining and paying salaries, controlling staff members’ hours and managing personnel insurance (work, accident, sickness, social and other). Important issues are workforce planning (see 3H), recruitment, CPD (3F), staff satisfaction and staff retention (3I). Annual performance appraisals should be conducted to compare the work performance and productivity of individual employees with the agreed objectives.
Data management
Prosthetics and orthotics service providers should collect data on the services delivered and on users, as this information is useful for planning, budgeting, monitoring and evaluating at both service delivery and national levels. Data should also be reviewed for quality management. Consistent collection and analysis of data provides a detailed picture of how successful the services are, for example in terms of productivity and in reaching certain target groups in different geographical areas (see 1O and 1P). Anonymized data should be sent to central level for analyses of national needs and service availability.

For effective analysis of data, service providers should have integrated computerized systems for storing and managing information and use electronic clinical records. The computer programs should allow easy access to data for reporting.

4R Quality management
Prosthetics and orthotics service providers must ensure that the quality of the products and treatments meets set requirements. A quality assurance system should therefore be in place, not only for the technical quality of prostheses and orthoses but also for the extent to which the services as a whole meet the needs of users (see Box 32). Quality management comprises measuring, monitoring and improving the quality of products and services (see Box 33). This corresponds to a clinical audit of health care services.

Box 32. Technical quality versus quality of services
The “quality” of a prosthetic or orthotic product might have slightly different meanings according to by whom and in which context it is used. In simple terms, a high-quality prosthesis or orthosis is one that is durable and safe and has excellent performance. From the perspective of the user, high-quality products not only meet those criteria but are comfortable, functional, aesthetically acceptable and meet their needs and expectations. From the economic point of view, a high-quality prosthesis or orthosis is a product that is durable and cost–effective. These criteria, with others, essentially define appropriate technology (see 2A).

The concept of quality should not be applied only to technical work but also to prosthetics and orthotics services in the broader sense. Services are of good quality when they are centred on the user, they are physically and financially accessible and free of other barriers, users feel they have been politely attended to, waiting times are short, few visits are needed, safety is ensured, the working processes are appropriate, the technical quality of the products is good and the continuity of services is ensured (including follow-up, maintenance, renewal of products and referral to other services). These aspects of service delivery all influence the trust of beneficiaries in the services, their willingness to seek assistance and to return to the centre if needed and their motivation to recommend the services to others. This, in turn, influences the overall outcome and impact of services.
Box 33. Quality management in prosthetics and orthotics services

Quality management comprises all the actions taken by a prosthetics and orthotics service provider to measure, monitor and improve the quality of products and services and to make sure that all the requirements of adequate service delivery are fulfilled. Quality management includes definition of quality indicators, which are measures of the quality achieved for each feature. It also involves definition of quality standards, which are the requirements to be met. Quality standards can be set by individual service providers but should be based on the best available evidence and in accordance with standards set at higher levels in the national system or, when applicable, by international bodies, such as ISO, WHO and ISPO. Quality standards should be realistic, so that the goals are attainable; they must therefore reflect the context in which the services are provided. Benchmarks may be set to measure the gradual improvements in quality that are to be expected over time.

Quality can be measured and monitored by, for example, structural and clinical testing (for technical quality, see 2H), analysing user satisfaction from questionnaires (to measure service quality), analysing service data and statistics (see 10) or occasional quality controls by external experts. Measurement and monitoring of quality can reveal quality-related problems and the actions required for quality improvement. The actions may include reviewing manufacturing processes (to make a product more resistant and durable) or changing appointment procedures and schedules (to reduce waiting times for users).

Any system that affects the quality of products and services, including management, administration, financial procedures, material procurement (including component choice), stock management and professional training, might have to be changed.

Quality assurance is not a one-off task but continuous work performed in a cycle (Fig. 6). Once problems are identified and actions taken to solve them, quality should be measured again to verify the improvements. Occasionally, quality indicators might have to be redefined to ensure that all the necessary aspects of quality are captured correctly. Similarly, standards may be adjusted gradually as quality improves.

Prosthetics and orthotics quality management should be an integral part of service provision. The responsibility for this work should be assigned to a clinical or technical staff member (in small units) or to a quality management team with representatives from various sections of the service. The opinions of users and caregivers should be carefully solicited to measure the quality of services, and feedback should be collected systematically from representative users, for example from questionnaires or focus group discussions. Service user representatives and disabled people’s organizations can play an important role in facilitating this work.
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