

STANDARDS FOR PROSTHETICS AND ORTHOTICS

Part 2: IMPLEMENTATION MANUAL

PRODUCTS

POLICY

PERSONNEL

PROVISION



USAID
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STANDARDS FOR PROSTHETICS AND ORTHOTICS

Part 2: IMPLEMENTATION MANUAL

WHO standards for prosthetics and orthotics

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

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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



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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.

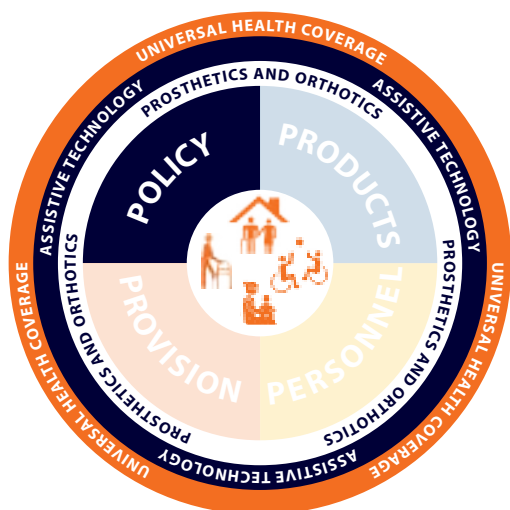
Scope and structure

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.



Area 1. Policy



1A 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.

1E 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.

▪ service establishment	= investment cost
<ul style="list-style-type: none"> ▪ training human resources ▪ service providers ▪ service users ▪ national monitoring 	= recurrent costs

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).

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.

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 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 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 policy-makers 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.

1J Universal health coverage

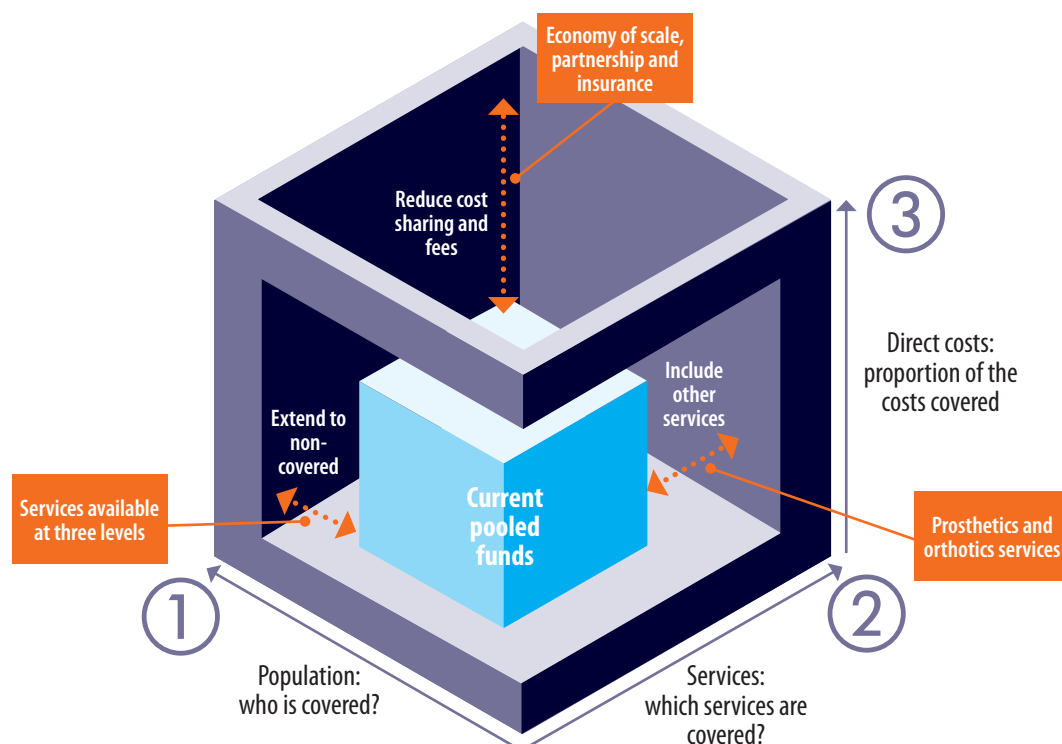
The concept

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.

Fig. 1. Three dimensions to be considered when moving towards universal health coverage



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).

1K 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).

1L 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.

1M 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. 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.

1N 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.

10 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 1. Examples of data that can be collected at service level**

Data	Purpose of data (examples)
Number of people treated and types of treatment provided	To understand the magnitude and breadth of services For planning procurement of components and materials
Socioeconomic status of users	To ensure that services also reach the most marginalized groups
Proportions of women and children among those assisted	To determine whether additional measures are needed to target these groups (such as increasing the number of female personnel)
Age groups	To ensure that children, young people and the elderly are included to the same extent as other age groups
Geographical origin of users	To determine the success of services in reaching remote parts of the intended catchment area
User experience (from questionnaires or focus group discussions)	To determine the quality, affordability and accessibility of services and factors that prevent use and compliance
Impact of the services on quality of life, participation and inclusion	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)
Waiting and delivery times	To indicate whether the services are user-friendly
Referrals (in and out): by and to whom and how	To determine the success of networking, awareness-raising and mechanisms for referral
Follow-up services: how many and who	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
Repair services: how often required, type, reason	To determine the technical quality of delivered products
Frequency of replacement of prostheses and orthoses	To determine the lifespan of products and therefore annual production needs
Abandonment of prostheses and orthoses, including rates and reasons	To determine quality issues and areas to be improved
Main causes of disability	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

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 (24) 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.

Box 7. Liaising with disability-inclusive sports and recreation programmes

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.



1R 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**

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

2E 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.)

2F 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).



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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).

2I 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 (4I). 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.

Box 11. Professional codes of conduct and ethics

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**



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

Area	Measure
Education	<ul style="list-style-type: none"> ▪ Attract the “right” students. ▪ Select students from rural areas. ▪ Train students close to rural communities. ▪ Facilitate professional development.
Regulatory interventions	<ul style="list-style-type: none"> ▪ Create the conditions for rural health workers to do more. ▪ Train personnel to meet rural needs. ▪ Make the most of compulsory service. ▪ Tie education subsidies to mandatory placements in rural areas.
Financial incentives	<ul style="list-style-type: none"> ▪ Make it worthwhile to move to a remote or rural area. ▪ Provide additional financial benefits.
Personal and professional support	<ul style="list-style-type: none"> ▪ Pay attention to living conditions. ▪ Ensure that the work-place is of an acceptable standard. ▪ Foster interaction between urban and rural personnel. ▪ Design career ladders for rural personnel. ▪ Facilitate knowledge exchange. ▪ Raise the profile of rural personnel.

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.



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Area 4. Provision of services



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)

(Box 13. continued)

Special attention must be paid to ensure that women, children and other vulnerable individuals are protected. The service provider must be able to respond to requests for treatment by personnel of the same gender and ensure that users can be accompanied if they wish.

Privacy and confidentiality: Privacy should be ensured in all phases of treatment and in all sections of the service unit. Any personal information collected by the service provider should be treated as confidential and not be shared without the consent of the user. Service providers should also ask users to consent to use of pictures or video clips of them before they are used in advertising, publications, case studies or other contexts.

Information: Service users and caregivers should receive complete information about the treatment process, suggested interventions, the outcome of assessments, the purpose and function of the proposed prostheses and orthoses, alternative treatments and cost implications. The expected outcomes, long-term benefits, possible risks, disadvantages and potential problems should be clearly explained. Personnel should also advise users and caregivers about the expected timelines and waiting times. For successful long-term results, personnel must clearly explain follow-up, the care and maintenance of products and where and how services for maintenance and repair can be accessed when required. The information should be accessible, for example printed in large format and in local languages.

Decision-making: Service users should have the final say on what is best for them. Prosthetics and orthotics personnel should help them in making an informed decision before they consent to the final treatment plan. Service users and caregivers should be encouraged to participate in the multidisciplinary team and be given opportunities to raise questions or concerns during and after treatment. Under no circumstances should users be forced to accept a particular intervention. They should be free to choose from the available alternatives, including components, materials and design, and their participation should always be voluntary.

Access to clinical records: In order for users and caregivers to be fully informed about their treatment and to participate actively in their treatment and decision-making, service providers must grant them full access to all information pertaining to their care, including their clinical records, throughout and after treatment.

Complaints and suggestions: Service providers should establish a system whereby users and caregivers can provide feedback on the services they received and how they were treated. This should include opportunities for anonymous presentation of concerns, complaints and suggestions.

4B 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

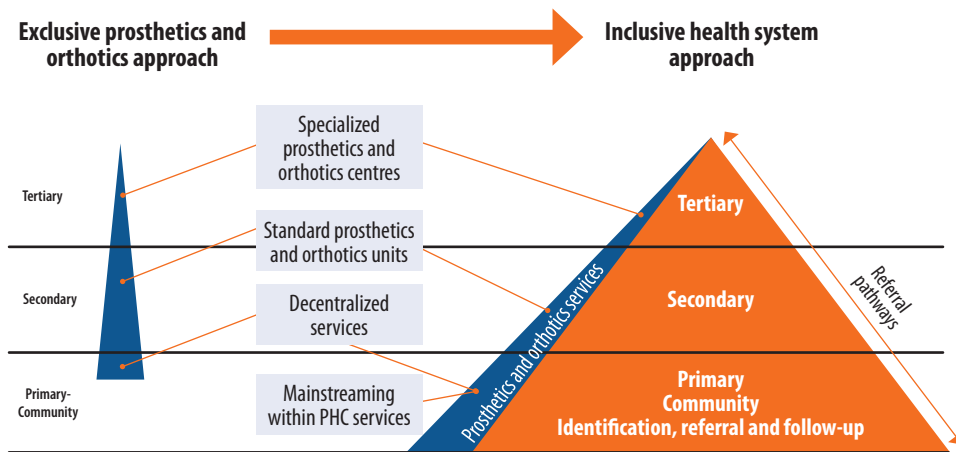
The number of service units required to cover the needs for prosthetics and orthotics in a country depends on the geographical setting, the types of service provided in each unit and their size and location. This varies widely by country.

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

Means of decentralization	Advantages	Disdvantages
Satellite services	<ul style="list-style-type: none"> ▪ Can provide the same range of services as the main service unit ▪ Can maintain the same quality standards as the main service unit ▪ Can be integrated into a health facility and stimulate collaboration with the health sector ▪ Can become a permanently staffed service unit 	<ul style="list-style-type: none"> ▪ The degree of decentralization is more limited than that of outreach and mobile services but can be increased by establishment of several units.
Mobile services	<ul style="list-style-type: none"> ▪ Can reach the least centralized parts of a country ▪ Are less dependent than outreach services on the main service unit and can be operational for longer ▪ Can be efficient and assist a large number of users ▪ Can play an important role in identification and referral of potential users ▪ Can assure a broad range of repair and maintenance work ▪ Can raise awareness about disability issues, prosthetics and orthotics needs and the role and benefits of the services 	<ul style="list-style-type: none"> ▪ Complicated cases and those requiring long training must be referred to a main service unit. ▪ The range of treatments and products that can be provided without compromising quality may be limited. ▪ Cost–effectiveness may be low.
Outreach services	<ul style="list-style-type: none"> ▪ Can reach the least centralized parts of a country ▪ Can identify and refer potential users ▪ Can assist some users 	<ul style="list-style-type: none"> ▪ Depend on the main service unit for fabrication of all custom-made products ▪ Insufficient time for the treatment of most users, who must be referred to a service unit ▪ High risk that the quality of treatment is below acceptable levels ▪ Only a limited range of treatments and products can be provided.
Linkage with CBR and other community programmes	<ul style="list-style-type: none"> ▪ Facilitates early identification and intervention ▪ Can refer potential users and follow them up after treatment ▪ Little cost for the prosthetics and orthotics service provider ▪ May increase the probability of co-financing services for community members ▪ Can do repairs and maintenance 	<ul style="list-style-type: none"> ▪ A very limited range of treatments can be provided; the vast majority of users have to travel to the service unit. ▪ The quality of treatments may be poor.
Linkage with community outreach campaigns	<ul style="list-style-type: none"> ▪ Can identify and refer potential users ▪ Little cost for the prosthetics and orthotics service provider 	<ul style="list-style-type: none"> ▪ Cannot provide prosthetics and orthotics treatment; all users have to be referred to a service unit

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 raise 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

Country example

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.

4I 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.


4J Service provision in disasters

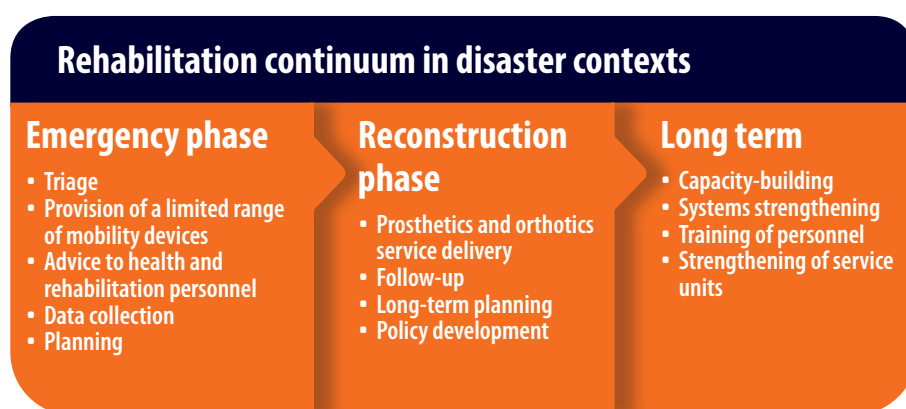
Prosthetics and orthotics services are often needed after natural and manmade disasters, such as earthquakes and civil conflict, with increasing numbers of people with acquired impairments such as spinal cord injury, traumatic brain injury, limb amputation, fracture, peripheral nerve injury and crush 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**



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.

4K 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

Service user areas

1

Reception/waiting area

- Waiting room
- Reception
- Toilets

2

Clinical area

- Assessment room
- Casting/measuring room
- Fitting room
- Gait training area
- Physiotherapy
- Shower room

Staff areas

3

Workshop area

- Assembly room(s), laboratory(s)
- Plaster modification room
- Plastic room
- Machine room
- Store
- In larger service units, facilities for a wider range of services may be available.

4

Personnel area

- Administration
- Staff offices
- Library/meeting room
- Changing room
- Shower room
- Toilets



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.

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

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

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.

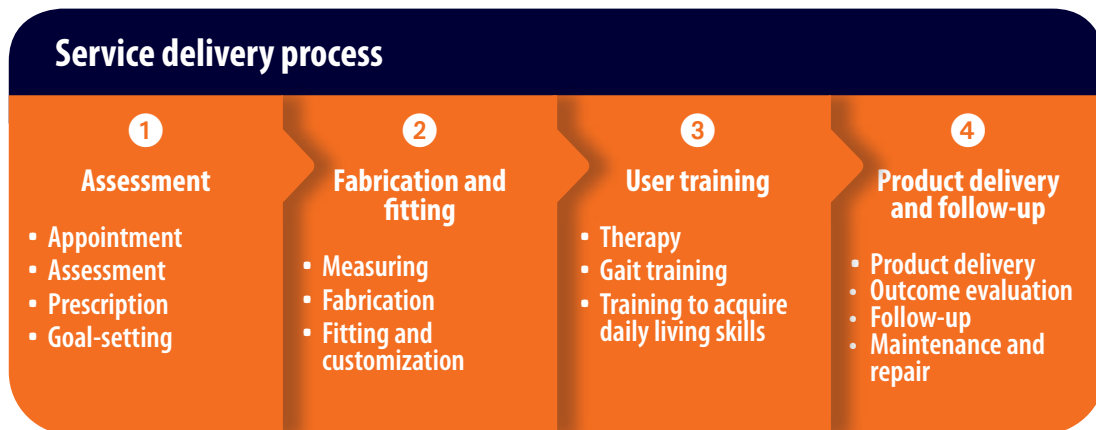
Self-referrals are common in many countries, particularly for the renewal of prostheses and orthoses. Renewals can usually be done with the original purchase requisition, if there is an agreement between the service provider and the paying office on how often and under what circumstances a new product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

 **Fig. 5. The prosthetics and orthotics service delivery process**



1 Assessment

Appointment

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.

2 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.

3 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).

4Q 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.

Fig. 6. The quality management (quality control) cycle



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.

References

1. United Nations Convention on the Rights of Persons with Disabilities. New York, NY: United Nations; 2006 (<https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/convention-on-the-rights-of-persons-with-disabilities-2.html>, accessed 30 August 2016).
2. ISO 8548-1: Prosthetics and orthotics – Limb deficiencies – Part 1: Method of describing limb deficiencies present at birth. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15796, accessed 30 August 2016).
3. ISO 9999:2011: Assistive products for persons with disability – classification and terminology. Geneva: International Organization for Standardization; 2015 (http://www.iso.org/iso/catalogue_detail.htm?csnumber=50982, accessed 30 December 2016).
4. ISO 22523:2006: External limb prostheses and external orthoses. Requirements and test methods. Geneva: International Organization for Standardization; 2006 (http://www.iso.org/iso/catalogue_detail.htm?csnumber=37546, accessed 30 June 2016).
5. Medical device regulations: global overview and guiding principles. Geneva: World Health Organization; 2003 (http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf, accessed 30 June 2016).
6. International Medical Device Regulators Forum (IMDRF) (<http://www.imdrf.org>, accessed 1 October 2016).
7. Gasser L, Slypen V, Miethe B, Abdullah H. ISPO cost calculation tool. Copenhagen: International Society for Prosthetics and Orthotics; 2006.
8. Global Clubfoot Initiative (<http://globalclubfoot.com/clubfoot>, accessed 1 October 2016).
9. Cavanagh PR, Lipsky BA, Bradbury AW, Botek G. Treatment for diabetic foot ulcers. *Lancet* 2005;366:1725-1735.
10. Negrini S, Donzelli S, Lusini M, Minnella S, Zaina F. The effectiveness of combined bracing and exercise in adolescent idiopathic scoliosis based on SRS and SOSORT criteria: a prospective study. *BMC Musculoskeletal Disord* 2014;15:263.
11. Global report on diabetes. Geneva: World Health Organization; 2016 (<http://who.int/diabetes/global-report/en/>, accessed 30 December 2016).
12. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005;293:217-228.
13. Cavanagh PR. Therapeutic footwear for people with diabetes. *Diabetes Metab Res Rev* 2004;20(Suppl 1):S51-S55.
14. de Oliveira AL, Moore Z. Treatment of the diabetic foot by offloading: a systematic review. *J Wound Care* 2015;24:560, 2-70.
15. Health financing for universal health coverage. What is universal coverage? Geneva: World Health Organization; 2016 (http://www.who.int/health_financing/universal_coverage_definition/en/, accessed 30 December 2016).
16. Health systems financing: the path to universal coverage. World Health Report. Geneva: World Health Organisation; 2010 (http://apps.who.int/iris/bitstream/10665/44371/1/9789241564021_eng.pdf, accessed 25 April 2017).
17. Options for financing and optimizing medicines in resource-poor countries. Discussion paper Number 7. Geneva: World Health Organization; 2010 (http://apps.who.int/iris/bitstream/10665/85708/1/HSS_HSF_DP.E.10.7_eng.pdf, accessed 25 April 2017).
18. Kutzin J, Yip W, Cashin C. Alternative financing strategies for universal health coverage in World Scientific Handbook of Global Health Economics and Public Policy 2016, 267-309.
19. Iezzoni LI, Frakt AB, Pizer SD. Uninsured persons with disability confront substantial barriers to health care services. *Disabil Health J* 2011;4:238-244.
20. Biddiss E, McKeever P, Lindsay S, Chau T. Implications of prosthesis funding structures on the use of prostheses: experiences of individuals with upper limb absence. *Prosthet Orthot Int* 2011;35:215-224.
21. Guidelines for training personnel in developing countries for prosthetics and orthotics services. Geneva: World Health Organization; 2005 (http://www.ispoint.org/sites/default/files/img/ispo-who_training_guidelines.pdf, accessed 30 August 2016).
22. International classification of functioning, disability and health: ICF. Geneva: World Health Organization; 2008 (<http://www.who.int/classifications/icf/en/>, accessed 30 June 2016).

23. Washington Group on Disability Statistics (<http://www.washingtongroup-disability.com/>, accessed 1 October 2016).
24. Article 31: Statistics and data collection. Convention on the Rights of Persons with Disabilities. New York, NY: United Nations; 2006 (<https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-31-statistics-and-data-collection.html>, accessed 30 August 2016).
25. Amputations and prosthesis register for lower extremity. Stockholm: Swedeamp; 2016. (<http://swedeamp.com/film14.htm>).
26. Magnusson L, Ahlström G. Experiences of providing prosthetic and orthotic services in Sierra Leone – the local staff’s perspective. *Disabil Rehabil* 2012;34:2111–2118.
27. Report of a consensus conference on appropriate prosthetic technology for developing countries. Phnom Penh, Cambodia. Copenhagen: International Society for Prosthetics and Orthotics, 1996.
28. Prosthetics and orthotics programme guide. Geneva: Landmine Survivors Network; 2006 (http://www.ispoint.org/sites/default/files/img/programme_guide_final_version.pdf, accessed 30 June 2016).
29. Chen RK, Jin Y, Wensman J, Shih A. Additive manufacturing of custom orthoses and prostheses – a review. *Additive Manufacturing* 2016;12:77–89.
30. Kate J, Smit G, Breedveld P. 3D-printed upper limb prostheses: a review. *Disabil Rehabil Assistive Technol* 2017;12:300–314.
31. Fisk JR, DeMuth S, Campbell J, DiBello T, Esquenazi A, Lin RS, et al. Suggested guidelines for the prescription of orthotic services, device delivery, education, and follow-up care: a multidisciplinary white paper. *Mil Med* 2016;181(2 Suppl):11–17.
32. Priority assistive products list. Geneva: World Health Organization; 2016 (http://www.who.int/phi/implementation/assistive_technology/global_survey-apl/en/, accessed 30 August 2016).
33. ISO 8549-1: Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15800, accessed 11 January 2017).
34. ISO 8549-2: Prosthetics and orthotics– Vocabulary – Part 2: Terms relating to external limb prostheses and wearers of these prostheses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15801, accessed 11 January 2017).
35. ISO 8549-3: Prosthetics and orthotics – Vocabulary – Part 3: Terms relating to external orthoses. Geneva: International Organization for Standardization; 1989 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15802, accessed 11 January 2017).
36. ISO 13405: Prosthetics and orthotics – Classification and description of prosthetic components. Parts 1, 2 and 3. Geneva: International Organization for Standardization; 2015.
37. ISO 13404: Prosthetics and orthotics – Categorization and description of external orthoses and orthotic components. Geneva: International Organization for Standardization; 2007 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=41480, accessed 11 January 2017).
38. Wyss D, Lindsay S, Cleghorn WL, Andrysek J. Priorities in lower limb prosthetic service delivery based on an international survey of prosthetists in low- and high-income countries. *Prosthet Orthot Int* 2015;39:102–111.
39. ISO 10328 Prosthetics – Structural testing of lower-limb prostheses – Requirements and test methods. Geneva: International Organization for Standardization; 2016 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=70205, accessed 11 January 2011).
40. Global priority research agenda for improving access to high-quality affordable assistive technology Geneva: World Health Organization; 2017 (<http://apps.who.int/iris/bitstream/10665/254660/1/WHO-EMP-IAU-2017.02-eng.pdf?ua=1>, accessed 23 March 2017).
41. Guidance paper on the supervision of assistant practitioners, BAPO standards for best practice. Paisley, Renfrewshire: British Association of Prosthetists and Orthotists; 2013 (<https://www.bapo.com/Framework/ResourceManagement/GetResourceObject.aspx?ResourceID=039ddb45-d3be-4b2d-9a26-0e3ff593b0a0>, accessed 30 June 2016).
42. Prosthetists/orthotists: standards of proficiency. London: Health and Care Professions Council; 2013 (http://hpc-uk.org/assets/documents/10000522Standards_of_Proficiency_Prosthetists_and_Orthotists.pdf, accessed 30 December 2016).
43. Physical rehabilitation programme: annual report 2013. Geneva: International Committee of the Red Cross; 2013 (<https://shop.icrc.org/e-books/physical-rehabilitation-programme-annual-report-2013.html>, accessed 30 June 2016).
44. Increasing access to health workers in remote and rural areas through improved retention. Geneva: World Health Organization; 2010 (http://apps.who.int/iris/bitstream/10665/44369/1/9789241564014_eng.pdf, accessed 30 December 2016).

45. Communiqué on major statistics of the second China national sample survey on disability. Beijing: National Bureau of Statistics of the People's Republic of China; 2006 (<http://www.china.org.cn/e-news/news061131-2.htm>, accessed 14 January 2017).
46. Battistella LR, Juca SS, Tateishi M, Oshiro MS, Yamanaka EI, Lima E, et al. Lucy Montoro Rehabilitation Network mobile unit: an alternative public healthcare policy. *Disabil Rehabil Assist Technol* 2015;10:309-315.
47. The relationship between prosthetics and orthotic services and community based rehabilitation. A joint ISPO/WHO statement. Copenhagen: International Society for Prosthetics and Orthotics; 2003 (<http://poi.sagepub.com/content/23/3/189.full.pdf>, accessed 30 June 2016).
48. Kumar S, Southard P, White M. Telemedicine: determining "critical to quality" characteristics for a healthcare service system design based on a survey of physical rehabilitation providers. *IEEE Engineer Manage Rev* 2016;44:41-55.
49. Khan F, Amatya B, Gosney J, Rathore FA, Burkle FM. Medical rehabilitation in natural disasters: a review. *Arch Phys Med Rehabil* 2015;96:1709-1727.
50. Reinhardt JD, Li J, Gosney J, Rathore FA, Haig AJ, Marx M, et al. Disability and health-related rehabilitation in international disaster relief. *Glob Health Action* 2011;4:7191.
51. Knowlton LM, Gosney JE, Chackungal S, Altschuler E, Black L, Burkle FM, et al. Consensus statements regarding the multidisciplinary care of limb amputation patients in disasters or humanitarian emergencies: report of the 2011 Humanitarian Action Summit Surgical Working Group on amputations following disasters or conflict. *Prehosp Disaster Med* 2011;26:438-448.
52. ISO 8549-4: Prosthetics and orthotics - Vocabulary - Part 4: Terms relating to limb amputation. Geneva: International Organization for Standardization; 2014 (<https://www.iso.org/standard/63536.html>, accessed 11 December 2016).
53. ISO 8548-2: Prosthetics and orthotics - Limb deficiencies - Part 2: Method of describing lower limb amputation stumps. Geneva: International Organization for Standardization; 1993 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=15798, accessed 11 December 2016).
54. ISO 8548-4: Prosthetics and orthotics - Limb deficiencies - Part 4: Description of causal conditions leading to amputation. Geneva: International Organization for Standardization; 1998 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=22327, accessed 30 December 2016).
55. ISO 8548-5: Prosthetics and orthotics - Limb deficiencies - Part 5: Description of the clinical condition of the person who has had an amputation. Geneva: International Organization for Standardization; 2003 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=36652, accessed 11 January 2017).
56. ISO 29782: Prostheses and orthoses - Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation. Geneva: International Organization for Standardization; 2008 (<https://www.iso.org/standard/45682.html?browse=tc>, accessed 11 January 2017).
57. ISO 29781: Prostheses and orthoses - Factors to be included when describing physical activity of a person who has had a lower limb amputation(s) or who has a deficiency of a lower limb segment(s) present at birth. Geneva: International Organization for Standardization; 2008 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=45681, accessed 11 January 2017).
58. ISO 29783-1: Prosthetics and orthotics - Vocabulary - Part 1: Normal gait. Geneva: International Organization for Standardization; 2008 (<https://www.iso.org/standard/45683.html>, accessed 11 January 2017).
59. ISO 29783-2: Prosthetics and orthotics - Vocabulary - Part 2: Prosthetic gait. Geneva: International Organization for Standardization; 2015 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=63539, accessed 11 January 2017).
60. ISO 8551: Prosthetics and orthotics - Functional deficiencies - Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis. Geneva: International Organization for Standardization; 2003 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=38506, accessed 11 January 2017).
61. ISO 29783-3: Prosthetics and orthotics - Vocabulary - Part 3: Pathological gait (excluding prosthetic gait). Geneva: International Organization for Standardization; 2016 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=66398, accessed 11 January 2017).
62. Baars EC, Schrier E, Geertzen JH, Dijkstra PU. Biomedical and psychosocial factors influencing transtibial prosthesis fit: a Delphi survey among health care professionals. *Disabil Rehabil* 2015;37:1946-1954.

POLICY

PRODUCTS

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