

# **Standards for Prosthetics and Orthotics Service Provision**

## **2015-2017 work plan**

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A joint information product planned by  
the Department of Essential Medicines and Health Products (EMP)  
and  
the Management of Noncommunicable Diseases, Disability, Violence and Injury Prevention (NVI)

Responsible officer:

Chapal Khasnabis,

Public Health, Innovation and Intellectual Property (PHI) Team

Department of Essential Medicines and Health Products (EMP)

Supported by: the International Society for Prosthetics and Orthotics (ISPO)

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# 1. Background and context

The Department of Essential Medicines and Health Products (EMP) and the Management of Noncommunicable Diseases, Disability, Violence and Injury Prevention (NVI) plan to create a new information product, namely, WHO Standards for Prosthetics and Orthotics Service Provision.

It concerns prosthetics and orthotics services for people with physical impairments including ageing populations, to maintain or improve their functioning and independence, facilitate participation, and enhance overall well-being.

- Prosthetics is a specialty within the field of health care technology concerned with the design, manufacture and application of prostheses.
  - Prosthesis (prosthetic device/product): externally applied device used to replace wholly, or in part, an absent or deficient limb segment (plural: prostheses). Common examples are artificial legs or hands.
- Orthotics is a specialty within the field of health care technology concerned with the design, manufacture, and application of orthoses.
  - Orthosis (orthotic device/product): externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems (plural: orthoses). Common examples are braces, splints and supports.

Prosthetics and orthotics are established disciplines in the field of health science and are often practiced together as they have lot of commonalities and both follow the same steps of service delivery<sup>1</sup>. Provision of prosthetics and orthotics devices are usually part of the secondary/tertiary care, habilitation and rehabilitation programs in particular. A prosthesis/orthosis enables a person with disability or functional impairment to remain active, productive and independent, participate in society and lead a healthy and dignified life. A good quality orthosis/prosthesis when appropriate to the user and the user's environment, has a significant impact on the level of independence of the user and reduces the need for formal support services (1).

## 2. Rationale

### 2.1 The need for Standards for Prosthetics and Orthotics Service Provision

Standards are needed to encourage better access to prosthetics and orthotics services.

According to the World Report on Disability, there are more than 1000 million people with disability worldwide, about 15% of the global population. Of this number, between 110 million and 190 million adults experience significant difficulties in functioning. It is estimated that some 93 million children – or one in 20 of those under 15 years of age – live with a moderate or severe disability (2). The majority of this population would benefit from prosthetics and orthotics services, if available within a country. The prevalence of disability is rising because of ageing populations and the global increase in chronic disease conditions. There is no definite data available at this stage but it is estimated that at least in excess of 100 million people (1.5 % of the world's population) are in need of prosthesis/orthosis.

The United Nations Convention on the Rights of Persons with Disabilities (CRPD) identified access to mobility aids, assistive devices and technologies as a human rights obligation that every Member State must fulfil and the importance of international cooperation to improve access (3). Despite that, today only 5–15% (approximately 1 in 10 persons) of the population in need has access to prosthetic and orthotic devices. The problem of accessing such devices is more acute in low- and middle-income countries. In this field, charities with non-trained professionals

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<sup>1</sup> The 8 steps of service delivery: 1 = referral and appointment, 2 = assessment, 3 = prescription (selection), 4 = funding & ordering, 5 = product preparation, 6 = fitting, 7 = user training, 8 = follow-up, maintenance and repairs.

often provide prosthetics and orthotics services meaning that service quality is compromised which results in poor quality and fit. This kind of intervention can also cause secondary complications. Without access to prosthetics and orthotics services, people are often confined to their homes – excluded from participating in society, and locked into poverty and isolation.

The current gap in access to such devices will be magnified in the future by the immense projected population growth, especially as the number of older people worldwide increases from 841 million in 2013 (11.7% of the world's population) to more than 2 billion (21.1%) by 2050 (4). There is a definite demographic shift in terms of people requiring prosthetics and orthotics services. In coming years, a growing population of prosthetics and orthotics users are going to be the elderly. In addition, successful guidance by WHO to address maternal health and child mortality means projected growth in the population of children with disabilities surviving and needing services. The present product range, service intervention, service delivery system, and training of personnel need to be redefined to accommodate this demographic shift.

Seeing the need for quality prosthetic and orthotic services, WHO published Guidelines for training personnel in developing countries for prosthetic and orthotic services in 2005 (5). These Guidelines made a definite impact globally and led to the establishment of many new prosthetics and orthotics training institutes with standardized course curricula, especially in the low- and middle-income countries (Fig. 1 and Fig. 2).

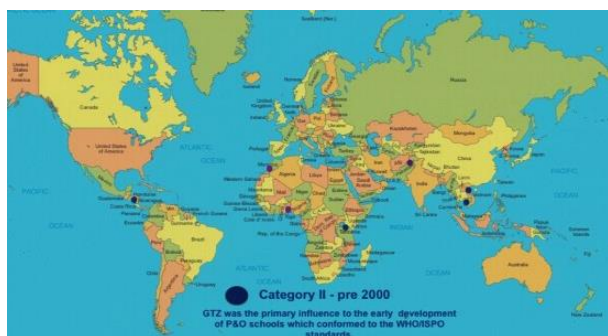


Figure 1: Number of training centres before 2000  
Source: ISPO



Figure 2: Number of training centres now.  
Source: ISPO

These training Guidelines were published to help transform the capabilities of the workforce, however, there remains no product to address the wider needs of prosthetics and orthotics services. This past training guideline was training specific and did not emphasise the whole service landscape or the whole workforce. There is a pressing need to address this situation by publication of WHO Standards for Prosthetics and Orthotics Service Provision to cover the whole of prosthetics and orthotics provision – delivery system, product, workforce, and policy. Such Standards will focus on a one-world approach to address both the pressures of demographic change and the low quality of services.

The proposed WHO Standards will also assist the International Society for Prosthetics and Orthotics (ISPO) to update their profession specific Information Packages Category I, Category II and Category III that describe the professional profile of Prosthetists/Orthotists and Prosthetics and Orthotics Technicians respectively.

The World Report on Disability outlined that worldwide existing training facilities for prosthetic and orthotic professionals and other providers of essential rehabilitation services are deeply inadequate in relation to the need (6). More professionals need to be trained but training alone would not solve the problem - equal focus is needed to develop the service provision. WHO published Prosthetics and Orthotics services in Developing countries – a discussion document in 1999 (7).

Existing discussion documents that include prosthetics and orthotics are significantly outdated and the need is for new Standards for Prosthetics and Orthotics Service Provision to address the current and emerging situation.

Emergence of the NCD and the ageing population are adding more demands for this sector to have comprehensive Prosthetics and Orthotics Standards with equal focus on products, policy, service provision, and workforce. More up to date state of the art information for countries or organizations wishing to develop, manage, monitor, innovate, and sustain prosthetic and orthotic services is very much needed. It is worth mentioning that no other organization or WHO departments are developing any such document. WHO is the leader on the issues related to prosthetics and orthotics service provision, has made a significant contribution for growth of this sector and also has the best expertise on this subject matter. The proposed standards will reinforce WHO's world leadership and normative guiding role.

## **2.2 Relevance to the departmental programme of work**

WHO 58th World Health Assembly resolution WHA58.23, "Disability, including prevention, management and rehabilitation" and the 66th World Health Assembly resolution WHA66.9 (2013), "Disability" highlights the importance of assistive technologies and urge the member States to facilitate access to appropriate affordable assistive technology. The WHO Global Disability Action Plan to improve health for all people with disability 2014–2021 highlights the need for development of prosthetics services and set indicators such as number of prosthetics and orthotics graduates from educational institutions per 10,000 population (Obj.2.2) and proportion of persons with disabilities that would receive the prosthesis and/or orthosis among other assistive devices (Obj.2.4) (8). The proposed Standards will assist WHO and the Member States to achieve the targets as outlined in the WHO Global Disability Action Plan 2014–2021 and to meet the aspiration of the Convention on the Rights for Persons with Disabilities (CRPD) and Universal Health Coverage.

The Department of Essential Medicines and Health Products (EMP) recently launched a new global initiative – Global Cooperation on Assistive Technology (GATE) (9). The main goal of this initiative is to improve access to high-quality affordable assistive health products including prosthetics and orthotics devices. WHO Member States would benefit significantly from comprehensive Standards for Prosthetics and Orthotics Service Provision. The proposed Standards will cover four key areas of the six building blocks detailed in "Everybody's Business: Strengthening Health Systems to improve Health Outcomes – WHO's framework for action," which are 1) service provision system, 2) products, 3) workforce and 4) policies including financing and cost benefits (10). The proposed standards will assist both NVI and EMP to fulfil its departmental mandate.

## **2.3 Director's approval**

This proposal has already obtained approval from the director of the department of the Essential Medicines and Health Products (EMP) and the Assistant Director-General of the Health System and Innovation (HIS) cluster of WHO. The EMP department will be primarily responsible for developing the Standards for Prosthetics and Orthotics Service Provision. EMP will collaborate with the department of the Management of Noncommunicable Diseases, Disability, Violence and Injury Prevention (NVI), the department of Ageing and Life Course (ALC), the regional and country offices to develop the Standards.

## **2.4 Funding**

Funding is from USAID and the EMP department.

## 2.5 Budget

A budget has been identified.

## 2.6 Timelines

There has been a very significant period of consideration of process in designing this plan.

Timeline (Gantt Chart)													
Steps	2015					2016					2017		
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
GRC advice to proceed with standards	█												
Steering group proposal refinement	█	█	█										
Consultation with SDG and ERG			█				█						
GRC advice/review on any recommendations								█					█
Initiate Commissioning of Systematic Review process			█	█									
Finalize selection and awarding the contract				█									
Commissioned Research takes place					█	█	█						
Drafting of Standards						█	█	█					
Meeting of the Standards Development Group							█						
Refine drafting									█	█	█		
Peer reviewing											█	█	
Finalize the Standards based on review feedback												█	█
Technical editing													█
Final approval													█
Printing publishing and Launching													█
Dissemination until ISPO World Congress 2017 (SA)													█

## 3. Target audience

The primary audience of the Standards for Prosthetics and Orthotics Service Provision will be the personnel responsible for rehabilitation services or tertiary care; prosthetics and orthotics service provision in particular. A secondary audience will be the policy-makers and leaders of health and social care providers, including representatives from the relevant government organizations and administrators. It will take a broad whole-of-government approach, acknowledging and articulating the importance of and linkages with, other Ministries such as Social Welfare that may provide prosthetics and orthotics services. The proposed Standards will also be relevant to the non-government actors; including faith-based organisations, not-for-profit organizations and the private sectors that often play important roles in the provision of prosthetics and orthotics services.

## 4. Persons affected by the standards

The primary group of people who will benefit from the Standards are obviously prosthetics and orthotics users. People with physical impairments (both temporary and permanent) and elderly people with physical functional decline will be the beneficiaries of evidence-based Standards. People affected by arthritis, diabetes, stroke, cerebral palsy, trauma, congenital anomalies, polio, leprosy and other people with conditions that lead to limb loss or functional limitation in limb or spine due to some other communicable and non-communicable diseases would benefit most out of the proposed Standards.

## **5. Related guidelines and publications**

### **5.1 WHO publications related to the planned standard**

WHO Guidelines on the provision of Manual Wheelchairs in less-resourced settings, published in 2008, WHO Community-Based Rehabilitation (CBR) Guidelines, published in 2008 (12) and WHO Guidelines on Health-Related Rehabilitation (Rehabilitation Guidelines), which is under development and the proposed Standards for Prosthetics and Orthotics Service Provision will complement each other and provide subject specific guidance to Member States. Due to lack of internationally accepted Standards, in many countries the quality of prosthetics and orthotics services are poor and as a result, people with disabilities or people in need of such services either reject the device or develop secondary health complications. To improve access to high-quality affordable medical/health products and specifically prosthesis and/or orthosis, it merits specific Standards to be applied to this distinct area of service provision.

### **5.2 Relevant publication produced by external organizations**

In 2008, the Landmine Survivors Network published a Prosthetics and Orthotics Services Programme and Project Guide in partnership with 35 international organisations (13, 14). These publications also recommended development of further detailed guidance, which has not yet been achieved. Organizations like the International Society for Prosthetics and Orthotics (ISPO), the International Committee of Red Cross (ICRC), the Handicap International and many Prosthetics and Orthotics Training Institutes have their own documents but nothing comprehensive.



## 6. Goal and objectives

The proposed Standards for Prosthetics and Orthotics Service Provision will support the Member States to implement UN Convention on the Rights for Persons with Disabilities (CRPD); especially Article 20: Personal Mobility and 26: Habilitation and Rehabilitation, and WHO Global Disability Action Plan 2014-2021, especially in realizing objective 2 – to strengthen and extend rehabilitation, habilitation, assistive technology, assistance and support services, and community-based rehabilitation. The proposed Standards will cover a key sector of assistive technology – prosthetics and orthotics (P&O) services. It would assist the stakeholders on how to develop, expand, and improve the quality of prosthetics and orthotics services.

Goal: To improve access to quality prosthetics and orthotics services.

The key objectives of the Standards are to advise on:

- The need for and benefit of prosthetics and orthotics services
- Cost-effectiveness of prosthetics and orthotics services – economic and social gain
- Competencies needed to deliver and manage quality prosthetics and orthotics services
- Delivery of prosthetics and orthotics service provision to improve access to quality prosthetics and orthotics services

The proposed Standards will provide policy-makers with advice to develop and strengthen prosthetics and orthotics services within existing health systems and/or physical rehabilitation programmes related to people with disabilities. Issues of quality, availability, accessibility, affordability, appropriateness and acceptability will underpin options and ways forward.

## 7. Contributors to standards development

In consultation with country and regional offices, WHO has already formed following three distinct groups to develop the proposed Standards for Prosthetics and Orthotics Service Provision.

### 7.1 Steering Group (SG)

The steering group comprises WHO staff members from headquarters, regional offices and country offices, who work directly on the issues related to prosthetics and orthotics intervention will constitute the Standards steering group. The primary tasks of the steering group will be:

1. developing the GRC application including scoping the Standards
2. selecting members for the standards development group (SDG) and external review group (ERG)
3. drafting the PICO questions and overseeing evidence retrieval
4. assisting in organizing standards development meetings
5. developing potential recommendations and
6. overseeing the writing and finalization of the standards.

Dr Jaffar Hussain, WHO Representative of Iraq would be the chair of the Standards Steering Group.

### 7.2 Development Group (DG)

WHO will engage key experts from the different stakeholder groups - prosthetics and orthotics providers and researchers, heads of prosthetics and orthotics training programmes, standards implementers, and public health professionals. Besides this, WHO will also engage users, a health economist, and an expert of Equity, human rights, and gender as active members of the SDG.

Careful consideration was given to ensure SDG to be multidisciplinary, gender and geographically- balanced. SDG members come with different skills-set and background, so that they could divide different tasks required to accomplish the job. WHO regional and country offices played a major role in selecting the members of the SDG.

SDG members will use Med-Net/SharePoint online collaborative platform, Skype or teleconference and emails to collaborate among themselves and will also have one face-to-face meeting. The role of this group will include:

1. determine the final PICO questions that the standards address
2. analyse the outcome of the systematic and other reviews
3. choose and rank outcomes
4. provide advice as required, on any modifications of the scope as established by the WHO steering group
5. write some of the sections
6. collect best practice examples
7. appraise the evidence used to inform the standards
8. advise on the interpretation of this evidence and
9. formulate the final statements

### **7.2.1 Technical experts**

Several technical content experts have been selected for SDG. A careful consideration was given to ensure that technical experts are from different WHO regions and with different level of expertise. Selection was made considering the expertise needed around the four priority topics of the proposed standards.

### **7.2.2 Health-economist**

A nominated Health Economist will be an active member of the group. Their research would bring the added value for development of the Standards. Their research experience, especially of systematic review would be useful to identify the potential economic benefits of prosthetics and orthotics interventions and cost with the suggested options or way forward.

### **7.2.3 Equity, human rights, and gender**

With knowledge and expertise, a nominated expert on control of bias will be able to contribute to the analysis and interpretation of evidence and determine how the intervention and possible recommendations can ensure their appropriateness in terms of gender, equity, and human rights.

## **7.3 Systematic review team**

The NVI department has already commissioned two systematic review groups to collect the scientific evidence related to assistive technology while developing the rehabilitation guidelines. Some of the related scientific evidence of the said exercise will be used for the proposed Standards for Prosthetics and Orthotics Service Provision. However to ensure a thorough systematic review on the subject matter, we will commission two teams of experts with the necessary expertise and no financial conflicts of interests for the systematic review(s) to capture the best available quantitative and qualitative evidence related to the prosthetics and orthotics provision.

The successful applicants(s) must be able to send two representatives per review to participate in a 4 day meeting of experts, namely the Standards Development Group from 9-12 November 2015 in Bangkok, Thailand, where they will present the interim results of the systematic review(s). Each systematic review team(s) will present each review in a PowerPoint presentation accompanied by soft and hard-copy executive summaries, analysis graphics, GRADE Evidence Profiles and Thematic summaries.

Furthermore they are required to submit all final documents, evidence tables and a final report of the systematic review(s) by 21<sup>st</sup> December 2015, the project deadline.

The responsible officer has already consulted SSG members, some of the SDG members and the methodologist to carry out a preliminary scoping exercise and draft the PICO questions. An open bidding process in the form of an open Request for Applications will be made to find the appropriate systematic review teams.

#### **7.4 External Review Group (ERG)**

This group is composed of people with different sets of expertise but being associated with prosthetics and orthotics, rehabilitation and health sector. Some of them also would implement the Standards once developed. They would be consulted during the different stages of the standards development process. They will review the final draft. The Standards Steering Group will be consulted to develop the ERG and a careful consideration will be given to ensure that like SDG, ERG is also multidisciplinary, gender and geographically- balanced. WHO regional and country offices played a major role in selecting the members of the ERG.

#### **7.5 Methodologist**

A methodologist has been selected to be the methodologist for the proposed Standards Document. They have been consulted in the planning process including developing the PICO questions.

#### **7.6 Stakeholders, including service users**

##### **7.6.1 End-users**

A nominated end user will ensure it is user-centred, especially in context of the low- and middle-income countries. They will ensure PICO questions and recommendations take into account the potential for differences in uptake and benefits for the users. Additional end-user participation and several ERG members with similar experience would honour the common sentiment of the Disabled Peoples Organizations, “Nothing about us without us.” They would also defend the positions of the individuals who are affected by the intervention bringing an invaluable perspective to the Standards development process.

#### **7.7 Observers at the meeting of the Development Group**

Considering the important role different stakeholders, reputed international organizations including United States Agency for International Development, the International Society for Prosthetics and Orthotics, International Committee of Red Cross, Mahidol University and others would be invited to the SDG meetings as observers.

## **8. Management of the Development Group**

### **8.1 Selection of the chair and vice-chair**

The WHO Standards steering group made a thorough search to find the most appropriate person to be the Chair of the group. Advice was sought from WHO country and regional offices. An expert has been selected to be the chair of the Standards Development Group. The chair will select a co-chair.

### **8.2 Group processes and decision-making**

Before engaging the SDG members, SSG members will formulate a structured plan and share delineating how decisions will be made with the SDG members in advance to have their views prior to their active engagement. The Chair and co-chair will be consulted before finalizing the decision making process including decision rules, process to mitigate to dissents, and finalization of the decision making model to be adopted in case of any dissent.

## **9. Conflict of interest**

### **9.1 Collecting disclosures of interest**

As outlined in the WHO Guidelines for Declaration of Interests (WHO Experts), EMP will obtain the Declaration of Interests (DOI) from every Group Member. The names and brief biographies of all the SDG/ERG members will be

placed in the WHO portal for public disclosure with a necessary disclaimer as outlined by the Compliance and Risk Management and Ethics (CRE).

## **9.2 Assessing disclosures of interest**

SSG will form a three-member subcommittee involving the responsible officer and two coordinators of Public Health Innovation and Intellectual Property (PHI) and Prevention of Blindness and Deafness, Disability and Rehabilitation (BDD) teams to do an initial review whether an interest has been declared by any of the SDG/ERG member, and if so, whether it is insignificant or whether it is potentially significant.

The sub-committee will do the necessary documentation to note that no relevant interest has been declared or such interest is insignificant or minimal. In case of having, a member with the “declared interest is significant or potentially significant”, the SDG/ERG member will be replaced.

# **10. Formulating key questions**

## **10.1 Background questions**

A small exercise involving the SSG members, methodologist, and some key experts has been carried out to identify the background research questions, which are as follows:

1. Why is access to quality prosthetics and orthotics services essential?
2. What are the economic and social benefits of prosthetics and orthotics services?
3. What are the risks of not providing access to prosthetics and orthotics services?
4. What kind of appropriate human resources are required to deliver and manage quality prosthetics and orthotics services?
5. What are the factors that need to be considered to ensure prosthetics & orthotics services become cost-effective?
6. What kind of service provision system is needed to improve access to quality prosthetics and orthotics services?

## **10.2 Foreground questions – priority topics**

Based on the requirement of the WHO Global Disability Action Plan 2014-2021, WHO Standards Steering Group (SSG) members have agreed that the following four priority topics for the proposed Standards for Prosthetics and Orthotics Service Provision, which are as follows:

1. access to quality prosthetics and orthotics services
2. cost-effectiveness of prosthetics and orthotics services
3. appropriate human resources for delivering and managing the prosthetics and orthotics services
4. Appropriate prosthetics and orthotics service provision system to ensure human rights and better quality of life of prosthetics and orthotic service users.

Based on the priority topics, the following PICO of the proposed Standards for Prosthetics and Orthotics Service Provision will be:

1. What is the effectiveness of prosthetics and orthotics services?
2. What is the cost-effectiveness of prosthetics and orthotics services?
3. What are the competencies needed to deliver and manage quality prosthetics and orthotics services?
4. What kind of service provision system is needed to improve access to quality prosthetics and orthotics products and services?

### 10.3 PICO questions

#### Priority Topic 1: Effectiveness of prosthetics and orthotics services

##### PICO 1.1:

<b>Population</b>	People with physical impairments or limb loss or functional limitations or deformities in limb or spine
<b>Intervention</b>	Provision of prosthetics/orthotics services
<b>Comparator</b>	Non-provision of prosthetics/orthotics services or provision of alternative assistive products (such as crutches, walkers, sitting board with castors, wheelchairs, and tricycles).
<b>Outcomes (primary)</b>	Coverage or access to services; prevention of fall/injuries; prevention of deformities or secondary health conditions; avoidance of premature deaths; disability adjusted life years (DALY)/ quality-adjusted life years (QALY); better health outcomes (functioning and quality of life); mobility and safety; user's satisfaction; cosmesis/image; building human capacity; time and physical burden for care services or givers.
<b>Outcomes (secondary)</b>	Human rights; empowerment; economical gain for individual and family; independence; self-confidence and self-esteem; educational and job opportunities; social acceptance; participation and inclusion.

#### Priority Topic 2: Cost-effectiveness of prosthetics and orthotics services

##### PICO 2.1:

<b>Population</b>	People with physical impairments or limb loss or functional limitations or deformities in limb or spine
<b>Intervention</b>	Investing in prosthetics/orthotics services
<b>Comparator</b>	Non investing in provision of prosthetics/orthotics services or providing alternative assistive products (such as crutches, walkers, wheelchairs, tricycles) or providing social support services (such as pension, social security, provision of caregiver/assistant).
<b>Outcomes (primary)</b>	Cost and cost-effectiveness; coverage or access to services; duration of stay in hospital/clinics; clinical output; prevention of secondary deformities or health conditions; completing the rehabilitation cycle or continuum of care; cost of future treatment of falls/injuries/secondary health conditions/deformities; better health outcomes (functioning and quality of life); user's satisfaction and availability of quality prosthesis/orthosis at an affordable cost; building human capacity; time and physical burden for care services or givers.
<b>Outcomes (secondary)</b>	Economical gain for the establishment/state; economical gain of individual and family; upholding human rights, educational and job opportunities; empowerment; social acceptance; participation and inclusion.

**Priority Topic 3: Competencies needed to deliver and manage quality prosthetics and orthotics services**

**PICO 3.1:**

<b>Population</b>	People with physical impairments or limb loss or functional limitations or deformities in limb or spine
<b>Intervention</b>	Quality education/training in prosthetics/orthotics of International Standard or as outlined in the WHO Guidelines for training personnel in developing countries for prosthetic and orthotic services (2005).
<b>Comparator</b>	Provision of prosthetic/orthotic service by personnel with non-accredited national/international training or online training or on the job training or no training.
<b>Outcomes (primary)</b>	Clinical output; prevention of secondary deformities or health conditions; fit and comfort; safety; savings from future treatment of falls/injuries/secondary health conditions/deformities; better health outcomes (functioning and quality of life); user's satisfaction; relationship with the clinical specialists and rehabilitation professionals; team work and availability of quality prosthesis/orthosis.
<b>Outcomes (secondary)</b>	Impact of health or rehabilitation services; quality of prosthetics and orthotics services; self-confidence and self-esteem; economical gain of individual and family; respecting human rights; educational and job opportunities; empowerment; social acceptance; participation and inclusion.

**Priority Topic 4: Prosthetics and Orthotics Service Delivery** Two PICO questions are identified:

**PICO 4.1:**

<b>Population</b>	People with physical impairments or limb loss or functional limitations or deformities in limb or spine
<b>Intervention</b>	Prosthetics or orthotics services with quality products/technologies as outlined by national standards or international standards published by bodies such as the International Organization for Standardization (ISO).
<b>Comparator</b>	Provision of prosthetic/orthotic service incorporating technologies or techniques or products not complying with national or international standards.
<b>Outcomes (primary)</b>	Clinical output; availability of quality products, durability, prevention of secondary deformities or health conditions, proper fit and comfort; safety, cost-savings from future treatment of falls/injuries/secondary health conditions/deformities; better health outcomes (improved functioning and quality of life); user's satisfaction; and availability of quality prosthesis/orthosis.
<b>Outcomes (secondary)</b>	Impact of health or rehabilitation services; quality of prosthetics and orthotics services; respect, self-confidence and self-esteem; economical gain of individual and family; educational and job opportunities; social acceptance, participation and inclusion.

**PICO 4.2:**

<b>Population</b>	People with physical impairments or limb loss or functional limitations or deformities in limb or spine
<b>Intervention</b>	<p>Tertiary/secondary level (national or regional) prosthetic/orthotic service provision</p> <p><b>Definition of tertiary level:</b> those services provided in a centre of expertise providing a full range of interventions and having a good linkage with primary/secondary level of health facilities. They usually represent the highest level of care in a country or large political division within a country.</p> <p><b>Definition of secondary level:</b> those services provided in a centre at regional/provincial/district-headquarter level providing common prosthetic and orthotic interventions and having a good linkage with primary level of health facilities and tertiary level service provision.</p>
<b>Comparator</b>	<p>Stand-alone prosthetic/orthotic service provision with no or poor link with the mainstream health facilities of the country.</p> <p>(Context: Prosthetics and orthotics services are not part of the health system in many countries, especially in low- and middle-income countries. In many countries, Ministry of Social Welfare or charities or NGOs with no or poor linkage with the mainstream health facilities of the country provide the prosthetics and orthotics services – mostly these are stand-alone models or they have branches in big cities but poor linkages with the health system.)</p>
<b>Outcomes (primary)</b>	Coverage or access to services; clinical output; prevention of secondary deformities or health conditions; proper fit and comfort; safety, cost-savings from future treatment of falls/injuries/secondary health conditions/deformities; better health outcomes (functioning and quality of life); user’s satisfaction; and availability of quality prosthesis/orthosis.
<b>Outcomes (secondary)</b>	Impact of health or rehabilitation services; quality of prosthetics and orthotics services; waiting period and service delivery costs; consumer costs, self-confidence and self-esteem; economical gain of individual and family; educational and job opportunities, social acceptance, participation and inclusion.

**10.4 Important and critical outcomes**

The critical and important outcomes will be determined in consultation with the SDG rating them according to the GRADE approach prior to the meeting using an electronic survey format. All Evidence profiles will include all critical outcomes, as these are the outcomes upon which options or recommendations should be based. GRADE rates outcomes as follows:

<b>RATING</b>	<b>IMPORTANCE</b>
9	Critical
8	Critical
7	Critical
6	Important

5	Important
4	Important
3	Not important
2	Not important
1	Not important

From discussions within the Steering Group the following outcomes are likely to be considered as critical:

- Comfort
- Pain
- Access to services
- Independence
- Participation
- Quality of Life
- Costs

However, the importance of each outcome is related to the specific intervention in each PICO and the final decision will be made by the SDG.

## 11. Preliminary Systematic Review

A preliminary search of the literature was conducted. A combination of search strategies was defined to find sources of information and to provide an indication of the published evidence base within selected healthcare databases. Other databases are advised in the systematic review phase of the standard development that would ideally include business, economic, education and engineering databases.

A wide general search about prosthetics and orthotics and services revealed over 19,000 references. Searches of title and abstract of articles published in the period 1995 to 2015 were then built up on a staged basis around the four priority topics. For this preliminary search only English language references were located.

References were found, selected and then screened (title and abstract) for closest relevance to the four priority topics. References that appeared to compare two or more specific types of prosthetic or orthotic device, rather than service, were excluded. 382 references were thus identified. These will be provided to the systematic review group(s).

During the preliminary search, it emerged that many authors do not differentiate between a single intervention and a service. For any future literature search, it would be advisable to consider including evidence on prosthetics and orthotics products and technologies (interventions) because this may reveal information about services of interest to the proposed standards.

Another finding was that in the literature, prosthetic users are described by the search terms that we have already identified, but orthotic users have a much broader range of descriptors. In a future search, more literature about orthotic users could be found by a diagnosis based research strategy.

Regarding workforce, additional searches about allied health should be used since there is an emerging trend of prosthetists and orthotists as allied health professionals globally.



## 12 Evidence to options or recommendations

Two different groups would carry out systematic reviews simultaneously. After completion of the systematic reviews and synthesis of the available evidence, the SDG with the support from the SSG will meet and assess the quality of evidence to formulate the options or evidence-based recommendations where necessary. During this exercise, the SDG will opt for the health service user’s perspective to ensure the users’ perceived benefits are prioritised. The systematic review teams and the methodologist will contribute most of the information required for the evidence specifically related to evaluating the balance of the benefits and harms and the quality of evidence.

### 12.1 Use of the GRADE framework

As outlined in the WHO handbook, the GRADE approach will be used to make judgments about the quantitative evidence. GRADE approach will assist the SDG to use the evidence generated out of systematic reviews to make statements about options or recommendations where required.

Also, considering the limitation of such evidence on the subject matter, the qualitative evidence will help to inform the standards, especially on issues related to the quality of life, values, equity and human rights. Gulmezoglu et al (15) discusses the emergence of reviews of qualitative evidence within a Cochrane review and explains that a quantitative review by a team of researchers investigating midwifery services was enriched by a qualitative review in the same subject area (16, 17). The qualitative review enhanced the decision-making process and helped the team to consider stakeholder values. The steering group intends to emulate this within the Standards for Prosthetics and Orthotics Service Provision.

### 12.2 Factors to consider, e.g. values and preferences; resource use; equity, human rights and gender

The GRADE framework will be adopted for use in presentation of the results and as a decision-making aid during the course of the SDG meeting. The nature of the GRADE framework allows for separation between the judgements on the quality of the evidence from the judgements on the strength of any recommendations. GRADE acknowledges that while the synthesis and quality of the evidence is an essential component of any recommendation formulation, other essential parameters must also be considered. In accordance with the revised version of the WHO Handbook the SDG will consider the factors outlined in the Table below when determining the direction and strength of any recommendation.

Factor	Decision	Source
Balance of Benefits vs Harms	Benefits > Harms Benefits = Harms Harms > Benefits	This information is primarily derived from the systematic review evidence
Quality of Evidence	High, Moderate, Low, Very Low	This information is primarily derived from the systematic review evidence
Values and Preferences (relates to those of the end-user)	No Major Variability Major Variability	Research data from both quantitative and qualitative will ideally inform this; where this is not available, the expertise and experience of the SDG members (especially end-users and experts in gender, equity, and human rights) will assist in evaluating the values and preferences
Costs	Less resource-intensive More resource-intensive	Data on costs will be collated where this is available prior to the SDG Meeting. The SDG will consider not only the cost of technology but also the training required to deliver it

Acceptability	Yes, no, uncertain	This refers to the acceptability not only to the end-user, but to the health worker and the system. The expertise and experience of the SDG members will assist in evaluating this
Feasibility	Yes, no, uncertain	The SDG will consider the requirements for each technology and service model from their knowledge and experience
Equity, and human rights	More or less equitable and human rights - yes, no, uncertain	The SDG will consider whether provision or implementation of a recommendation is likely to lead to greater equity or not and realization of human rights or not

All of the above parameters will be presented to the SDG and would be considered together to derive a recommendation based on each PICO. A recommendation will be in the format of a statement based on the question posed in the PICO. There are two key components of a recommendation:

### 1. Direction of the recommendation

The SDG will consider all the parameters outlined in the Table above and determine if they are in support of recommending the intervention under consideration or whether they are against it.

### 2. Strength of the recommendation

After determining the direction of the recommendation, the SDG will consider the strength of the recommendation. This can either be strong or conditional as defined below:

A strong recommendation implies that the SDG is *confident* that the desirable effects of adherence to the recommendation outweigh the undesirable effects (or vice versa)

A conditional recommendation implies that the SDG concludes that the desirable effects of adherence to the recommendation *probably* outweigh the undesirable effects (or vice versa), but is not confident

Conditional recommendations are often driven by lower quality evidence and context-specific settings e.g. when implementation of a recommendation is possible in settings where resources are available but not possible in more resource-constrained settings.

If there is no evidence and the SDG is not able to make a recommendation, a note will be made that no recommendation is made due to insufficient evidence. In such a case, the SDG will attempt to provide options that programme managers may consider but these will not be prioritised or placed in a hierarchy and it will be clearly noted that the options are derived from expert opinion.

## 12.3 Tools for formulating options or recommendations

SDG will use following tools to formulate options or recommendations:

1. Decision-making tables
2. Presentation
3. Flip-chart group process

### **12.3.1 Decision-making Table**

This SDG will require each PICO to be presented within a Decision-making (DM) Table. The DM table will be completed prior to the meeting as far as possible and will include each of the parameters required for decision-making as outlined in the Table of parameters above. The source of the data will be presented within the DM table.

### **12.3.2 Presentation of systematic reviews and Evidence Profiles**

The systematic review team(s) will present each review in a PowerPoint presentation accompanied by hard-copy executive summaries, analysis graphics, GRADE Evidence Profiles and Thematic summaries. These will be linked to allow the SDG ease of cross-referencing between the presentations and hard-copies.

(Note: during the review process, each team will use the EndNote reference manager software web version to manage references and share data to avoid duplication of effort).

### **12.3.3 Flip-chart group process**

During the SDG Meeting the methodologist will facilitate the group decision-making by using a DM table on a flip-chart to allow the group to consider each parameter separately. This verbal and visual process will allow for transparent and explicit processes to final decision-making.

Wherever possible, the group will be encouraged to reach consensus on both the direction and strength of each recommendation or the group will provide options. In the event that consensus is not obtained, an open (not secret) voting procedure will be implemented. At the first session of the SDG the group will determine together an appropriate voting result ratio to finalise any recommendation e.g. 50/50 or 60/40 or 70/30.

## **13. Producing and publishing**

### **13.1 Standard format**

Standards for Prosthetics and Orthotics Service Provision will follow WHO routine format with an executive summary containing the key options and recommendations of the Standards, a main body and appendices.

### **13.2 Peer review**

After the approval of the Zero draft by the SDG, the document will be sent to the ERG for their review along with the WHO relevant departments, regional offices and some selected country offices. In case of any major concerns arising out of the peer review process, SDG will be duly consulted. The responsible officer with the help of the writer would finalize the document after due peer review process and develop the final document for the GRC approval/executive clearance if recommendations are to be made.

### **13.3 Writing the document**

WHO would nominate an expert as the main author/writer for the standards. They would be responsible for incorporating review comments and finalizing the document. They would be assisted by the responsible officer and some designated members of the SSG and SDG.

### **13.4 Editing, proofreading, layout and publication**

The responsible officer will follow the WHO normal procedures to obtain GRC Review/executive clearance if recommendations are to be made. Once approved, it will be shared with the designer for layout. The proposed Standards for Prosthetics and Orthotics Service Provision will be published in both hard and soft format. An electronic version will be available from the WHO website for easy download. The proposed Standards will be translated in all six UN languages in a phased manner.

### **13.5 Updating**

Though ideally any information product should be reviewed within 5 years from its day of the launch but due resource constraints, it is expected to take a longer time for its full implementation and demand for update. Hence, it is proposed that the proposed standards would be updated after 10 years or 2027.

## **14. Implementation and evaluation**

### **14.1 Implementation**

Dissemination and implementation of Standards for Prosthetics and Orthotics Service Provision will be done by WHO headquarters, regional and country offices and fits well within departmental programme of NVI and EMP.

Publication of these Standards is very crucial to realise the outcomes of the 66th World Health Assembly resolution WHA 66.9, WHO Global Disability Action Plan 2014–2021 and fulfil the key objectives of the GATE initiative. The proposed Standards will position prosthetics and orthotics services within the context of the Universal Health Coverage and will ensure better prosthetics and orthotics service provision worldwide, especially in low- and middle-income countries. WHO, its collaborating centres and partners would assist translations of the Standards into regional languages and support local adaptations/implementation.

### **14.2 Evaluation**

WHO will constantly monitor implementation of the Standards for Prosthetics and Orthotics Service Provision using WHO regional and country offices. Within 5 years from the date of launch, WHO would organize the first evaluation and another one after 8 years to assess the usefulness and impact of the Standards. Findings of the evaluation would be used in updating the Standards in the future.

# Appendix

## Standards steering group

Chair: Dr Jaffar Hussain, Head of WHO Iraq country office.

	Family name	Name	Affiliation	Expertise
1	Khasnabis	Chapal	EMP/PHI	P&O/Assistive Health Technology
2	Mirza	Zafar	EMP/PHI	Psychiatrist
3	Pupulin	Andrea	EMP/PHI	P&O/Philosophy and International Development/researcher
4	Cieza	Alarcos	NVI/BDD	Psychologist
5	Vasquez	Armando Jose	PAHO/AMRO	Physiatrist
6	Kleinitz	Pauline	WPRO	Physiotherapist
7	Sakr	Hala	EMRO	Medical Officer
8	Mishra	Satish	Tajikistan/ EURO	Occupational Therapist
9	Mallick	Maryam	Pakistan/ EMRO	Medical Officer
10	Hussain	Jaffar	Iraq, EMRO	Medicine and Public Health, ex-regional adviser of Disability and Rehabilitation

# Appendix

## Standards development group

Nominated, selected and invited. Subject to Declarations of Interest.

# Appendix

## External review group

Nominated, selected and invited. Subject to Declarations of Interest.

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