A Market Landscape and Strategic Approach to Increasing Access to Prosthetic Devices and Related Services in Low- and Middle-Income Countries

PRODUCT NARRATIVE:

PROSTHESES

AT2030

ATscale
GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY
atscale2030.org

APRIL 2020

ACKNOWLEDGEMENTS

This report was delivered by the Clinton Health Access Initiative under the AT2030 programme in support of the ATscale Strategy. The AT2030 programme is funded by UK aid from the UK government and led by the Global Disability Innovation (GDI) Hub. The authors wish to acknowledge and thank prosthetics sector experts, practitioners and users, and the partners from the AT2030 programme and Founding Partners of ATscale, the Global Partnership for Assistive Technology, for their contributions. The Founding Partners are: China Disabled Persons' Federation, Clinton Health Access Initiative, GDI Hub, Government of Kenya, International Disability Alliance, Norwegian Agency for Development Cooperation, Office of the UN Secretary-General's Envoy for Financing the Health Millennium Development Goals and for Malaria, UK Department for International Development, UNICEF, United States Agency for International Development, World Health Organization.

The views and opinions expressed within this report are those of the authors and do not necessarily reflect the official policies or position of ATscale Founding Partners, partners of the AT2030 programme, or funders.

Please use the following form: ***(https://forms.gle/kQdJTR9uXRj8g5aYA)*** to register any comments or questions about the content of this document. Please direct any questions about ATscale, the Global Partnership for Assistive Technology, to ***info@atscale2030.org*** or visit ***atscale2030.org***. To learn more about the AT2030 Programme, please visit ***at2030.org***.

TABLE OF CONTENTS

ACRONYMS

APDK	Association of Physically Disabled Kenya
AT	Assistive technology
BMVSS	Bhagwan Mahaveer Viklang Sahayata Samiti
CBR	Community-based rehabilitation
CE	CE marking (compliance with EU legislation)
CEPO	Centre of Excellence for Prosthetics and Orthotics
CHAI	Clinton Health Access Initiative, Inc.
CSO	Civil society organisation
CSPO	The Cambodian School of Prosthetics and Orthotics
DPO	Disabled persons' organisation
EUR	Euro (currency)
FBO	Faith-based organisation
FDA	US Food and Drug Administration
HI	Humanity & Inclusion (formerly Handicap International)
HIC	High-income country
HR	Human Resources
ICRC	International Committee of the Red Cross
ISPO	International Society for Prosthetics and Orthotics
ISO	International Organization for Standardization
LMIC	Low- and middle-income country
NGO	Non-governmental organisation
OADCPH	Organisation Africaine pour le Développement des Centres pour Personnes Handicapées
OOP	Out-of-pocket
P&O	Prosthetics and orthotics
PPP	Public-private partnership
SOL	Scandinavian Orthopaedic Laboratory (Sweden)
SRA	Stringent Regulatory Authority
TATCOT	Tanzania Training Centre for Orthopaedic Technologists
TF	Transfemoral (prosthesis)
TT	Transtibial (prosthesis)
UK	United Kingdom
US	United States of America
USD	United States Dollar
USAID	United States Agency for International Development
WHO	World Health Organization
3D	Three-dimensional (printing)

EXECUTIVE SUMMARY

TO ACCELERATE ACCESS TO ASSISTIVE TECHNOLOGY (AT), it is critical to leverage the capabilities and resources of the public, private, and non-profit sectors to harness innovation and break down barriers to affordability and availability. Market-shaping interventions can play a role in enhancing market efficiencies, as well as coordinating and incentivising stakeholders involved in demand- and supply-side activities. This document will address the key barriers and opportunities to increase access to prostheses services. Since there is a significant overlap in prosthetic and orthotic service delivery, access to orthotic services will also benefit from the proposed interventions.

Globally, an estimated 1.5 million people undergo amputations every year and need to access prosthetic services. The need is growing in low- and middle-income countries (LMICs). However, despite evidence that using a prosthesis can improve quality of life and reduce mortality for amputees, the World Health Organization (WHO) estimates that only 5-15% of amputees who need prosthetic devices in LMICs have access to them.

The market for prosthetic solutions in LMICs is small, because prostheses need to be fitted through a service delivery process that requires specialised infrastructure and personnel, both of which are in short supply in LMICs. Governments have historically not invested in this sector, because they lack data and awareness of the need and economic benefits. In the absence of government investments, non-governmental organisations (NGOs) have developed service capacities, largely in response to emergencies that sometimes operate in parallel to government systems. Without support from governments and donors to integrate provision and expand capacity, prostheses are not accessible to most people that need them. Innovative socket manufacturing technologies, including digital fabrication and direct-casted sockets, have the potential to increase access. However, consensus is needed within the sector on the readiness of these technologies to be deployed in LMIC markets.

A few companies supply most of the prosthetic components worldwide, and these are focused on high-income markets that can bear more expensive and technologically advanced solutions. Alternative suppliers offering affordable products are entering LMICs from emerging markets such as China, Turkey, and India. However, limited transparency on the quality and performance of these components in LMIC contexts inhibit their uptake. Additionally, prosthetic components should be available through a flexible and responsive supply chain, since component selection is made by prosthetists/orthotists based on assessments of users' needs and use context. While components in high-income countries (HICs) are often ordered individually from the manufacturer, logistics challenges in LMICs may not allow such an approach. An opportunity exists to increase access to affordable, quality, and appropriate prosthetic components, but will require more transparency and a more responsive supply chain.

High prices and poor perception of value of prosthetic services in LMICs, combined with high indirect costs for users to travel, makes prosthetic services unaffordable to many of people who need them. Prosthetic services can be made more affordable by: 1) increasing the number of service units (in particular, by leveraging decentralised service models and the innovative technologies that enable them); 2) establishing reimbursement schemes that encapsulate all costs to the user; and 3) leveraging alternative forms of financing for both capacity-building and user financing.

An opportunity exists to transform access to prosthetics services and products in LMICs, but this will require a coordinated effort between: 1) governments to expand service capacity; 2) global stakeholders to provide guidance on products and technologies; 3) suppliers to expand market presence and offerings; and 4) donors to support these activities. To accelerate access to prosthetic services in LMICs, the following strategic objectives have been defined:

- **STRATEGIC OBJECTIVE 1:** Develop foundational datasets to inform the investment case for prosthetic services and guide the development of standards.
- **STRATEGIC OBJECTIVE 2:** Support countries to define appropriate policies and invest in the key requirements of a functioning prosthetic provisioning system.
- **STRATEGIC OBJECTIVE 3:** Accelerate market validation and adoption of innovative technologies that can simplify, decentralise, and lower the cost of prosthetic service provision.
- **STRATEGIC OBJECTIVE 4:** Accelerate the uptake of affordable, quality prosthetic components by increasing market transparency to empower buyers to make value-based purchasing decisions.
- **STRATEGIC OBJECTIVE 5:** Strengthen regional supply mechanisms to increase affordability and availability of quality prosthetic components.

These strategic objectives are supplemented by initial activities to support access to affordable, high-quality, and appropriate prosthetic devices and services. ATscale, the Global Partnership for Assistive Technology, is currently in the process of developing a prioritisation process to inform which of the market-shaping activities proposed in this document will be incorporated into the Partnership's action and investment plan in order to guide activities and investments in the short-term. While that is underway, some of these proposed activities will be undertaken in the immediate term by the AT2030 programme, funded by UK aid, in line with its aim to test what works to increase access to affordable and appropriate AT.

INTRODUCTION

1. Assistive Technology and Market Shaping

Assistive technology (AT) is an umbrella term covering the systems and services related to the delivery of assistive products such as wheelchairs, eyeglasses, hearing aids, prosthetics, and personal communication devices. Today, well over 1 billion people require AT to achieve their full potential, but 90% do not have access to the AT that they need. This unmet need for AT is driven by a lack of awareness of this need, discrimination and stigma, a weak enabling environment, lack of political prioritisation, limited investment, and market barriers on the demand and supply side. Market shortcomings limit availability, affordability, and access to appropriate AT, and market shaping is proposed to address these root causes, as well as serve the wider aim of ensuring improved social, health, and economic outcomes for people who require AT. Increased access to AT is critical to achieve many global commitments, including universal health coverage, the ideals of the United Nations Convention on the Rights of Persons with Disabilities, and the ambitious Sustainable Development Goals. To accelerate access to AT, the global community needs to leverage the capabilities and resources of the public, private, and non-profit sectors to harness innovation and break down market barriers.

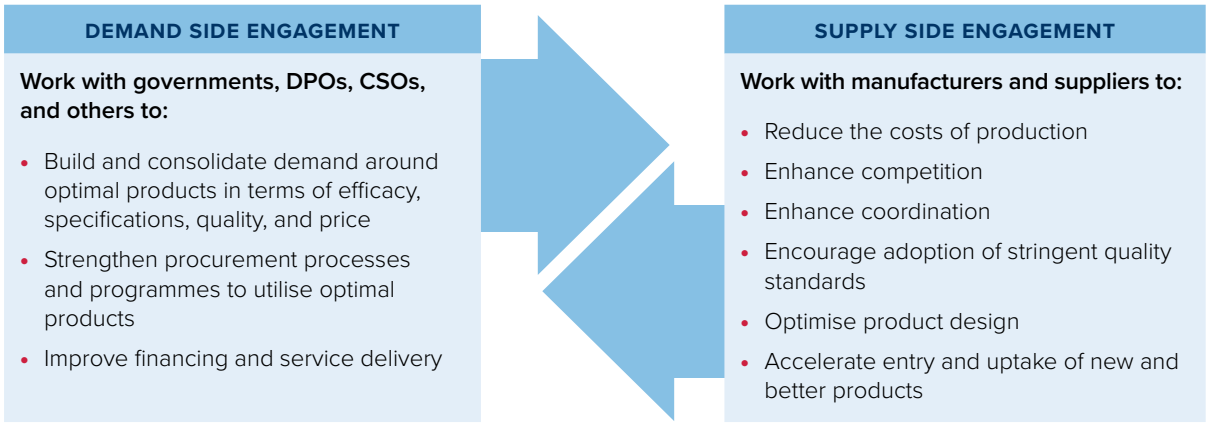
Whether by reducing the cost of antiretroviral drugs for HIV by 99% in 10 years, increasing the number of people receiving malaria treatment from 11 million in 2005 to 331 million in 2011,[1] or doubling the number of women receiving contraceptive implants in 4 years while saving donors and governments USD 240 million,[2] market shaping has addressed market barriers at scale. Market-shaping interventions can play a role in enhancing market efficiencies, improving information transparency, and coordinating and incentivising the numerous stakeholders involved in both demand- and supply-side activities. Examples of market-shaping interventions include: pooled procurement, de-risking demand, bringing lower cost and high-quality manufacturers into global markets, developing demand forecasts and market intelligence reports, standardising specifications across markets, establishing differential pricing agreements, and improving service delivery and supply chains.

Market-shaping interventions often require coordinated engagement on the demand and supply side (see Figure 1). Successful interventions are tailored to specific markets after robust analysis of barriers and seek to coordinate action on both the demand and supply side. These interventions are catalytic and time-bound, with a focus on sustainability, and are implemented by a coalition of aligned partners providing support where each has comparative advantages.

[1] UNITAID and World Health Organization. UNITAID 2013 Annual report: transforming markets saving lives. UNITAID; 2013. Available from: http://unitaid.org/assets/UNITAID_Annual_Report_2013.pdf.

[2] Suzman M. Using financial guarantees to provide women access to the modern contraceptive products they want to plan their families. Bill & Melinda Gates Foundation and World Economic Forum; 2016 May. Available from: http://www3.weforum.org/docs/GACSD_Knowledge%20Hub_Using_Financial_Guarantees_To_Provide_Women_Access_To_Modern_Contraceptives.pdf.

FIGURE 1: ENGAGING BOTH DEMAND AND SUPPLY SIDE FOR MARKET SHAPING



Historically, AT has been an under-resourced and fragmented sector and initial analysis indicated that a new approach was required. ATscale, the Global Partnership for Assistive Technology, was launched in 2018 with an ambitious goal to provide 500 million people with the AT that they need by 2030. To achieve this goal, ATscale aims to mobilise global stakeholders to develop an enabling ecosystem for access to AT and to shape markets to overcome supply- and demand-side barriers, in line with a unified strategy (https://atscale2030.org/strategy). While the scope of AT is broad, ATscale has focused on identifying interventions needed to overcome supply- and demand-side barriers for five priority products: wheelchairs, hearing aids, eyeglasses, prosthetic devices, and assistive digital devices and software.

Clinton Health Access Initiative (CHAI) is delivering a detailed analysis of the market for each of the priority products under the AT2030 programme (https://www.disabilityinnovation.com/at2030), funded by UK aid from the UK government, in support of the ATscale Strategy. AT2030 is led by the Global Disability Innovation Hub. What follows is a detailed analysis of prosthetic devices, one of the five evaluated priority products.

2. Product Narrative

The product narrative defines the approach, identified by CHAI, to sustainably increase access to high-quality, affordable AT in LMICs. The goals of this narrative are to: 1) propose long-term strategic objectives for a market-shaping approach; and 2) identify immediate opportunities for investments to influence the accessibility, availability, and affordability of prosthetic and orthotic (P&O) services. This document will focus primarily on access to prosthetic services. However, given the overlap between P&O service delivery in infrastructure and personnel, access to orthotic services will also benefit from the proposed interventions.

This report has been informed by desk research, market analysis, key informant interviews, and site visits with relevant partners and governments to develop a robust understanding of the market landscape and the viability of the proposed interventions. A list of all individuals interviewed or consulted during the development process can be found in Annex A. This document is divided into two chapters:

- **CHAPTER 1: MARKET LANDSCAPE,** including market context, the current product landscape, state of access and provision, supply chain analysis, and stakeholders' current engagement, as well as key market challenges and barriers to access on both the demand and supply side;
- **CHAPTER 2: STRATEGIC APPROACH TO MARKET SHAPING,** including strategic objectives highlighting the long-term outcomes required to shape the market. A series of immediate next steps or actions to support achieving each strategic objective are proposed. For any given objective, the interventions are discrete testable opportunities that support the development of longer-term scalable interventions and investments.

CHAPTER 1

MARKET LANDSCAPE

3. Market Context

3.1 There are an estimated 65 million people that live with limb amputations globally, with 1.5 million people undergoing amputations – mostly lower limb – each year. Most amputees need access to prosthetic services and this need is expected to double by 2050.

No comprehensive data exists on the global incidence of amputations, but a recent study estimated that 65 million people live with limb amputations globally.[3] Amputation is the action taken to surgically remove a part of the body following trauma, disease, or congenital conditions and is the leading reason for the use of prosthetic devices. A prosthetic device is an externally applied device used to replace wholly or in part an absent or deficient limb segment. An orthotic device is an externally applied device used to modify the structural and functional characteristics of the neuro-muscular and skeletal systems.[4] Both are fitted using common biomechanics, processes, and equipment. WHO groups P&O together since both concern the use of externally applied devices to restore or improve mobility, functioning, and to correct deformities. Although P&O services have overlapping human resource and infrastructure requirements, this document will focus on the market barriers to access for lower-limb prostheses since more than 60% of the 1.5 million amputations every year are lower limb.[3] However, as a result of investing in the scale-up of prosthetic services, access to orthotic services is also expected to also expand due to an increase in the number of service points and trained personnel in LMICs.

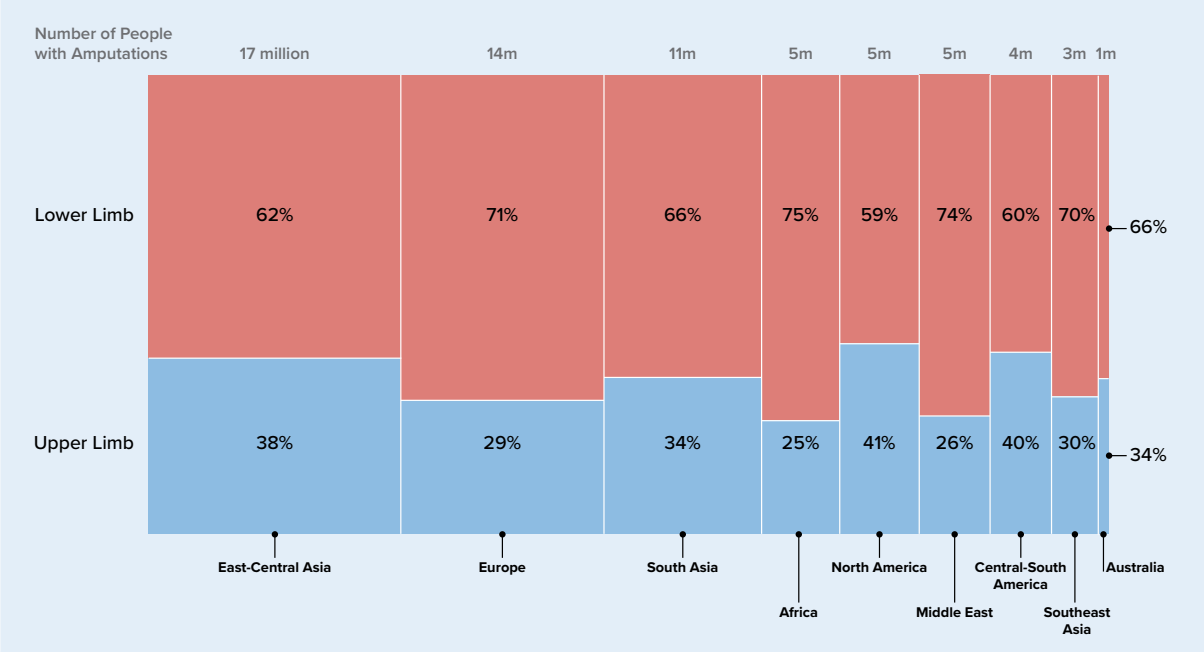
An estimated 64% of people living with amputations are in LMICs.[3] Regionally, about half are situated in Asia (see Figure 2). The primary causes for amputation differ between HICs and LMICs. In HICs, around 80% of amputations are caused by complications of blood vessel diseases and diabetes[5] that restrict blood flow to various parts of the body. Foot ulcers, a common complication of sensory loss due to poorly controlled diabetes, account for the majority of lower-limb amputations among diabetics.[6] In LMICs, on the other hand, most amputations result from trauma due to road traffic accidents, injury from current or past conflicts, infections of the bone or tissue such as osteomyelitis or sepsis, and untreated birth defects.

The global need for prosthetic devices is expected to double by 2050.[7] More amputations will take place in LMICs due to a growing population, increasing road traffic accidents due to poor road conditions and urbanisation, and changing demographics that lead to increasing prevalence of non-communicable diseases such as diabetes. For example, diabetic patients are eight times more likely to undergo at least

[3] McDonald CL, Westcott-McCoy S, Weaver MR, Haagsma J, Kartin, D. Global prevalence of traumatic non-fatal major limb amputation. Prosthet Orthot Int. Submitted 2020 March.
[4] International Organization for Standardization. ISO 8549-1:1989 Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses. 1989. Available from: https://www.iso.org/obp/ui/#iso:std:iso:8549:-1:ed-1:v1:en.
[5] Excess glucose damages blood vessels, leading to vascular diseases such as loss of sensation in extremities. 12-15% of people with diabetes will develop foot ulcers due to poor circulation, which increases their risk for infection and amputation.
[6] Wraight P, Lawrence S, Campbell D, Colman P. Retrospective data for diabetic foot complications: only the tip of the iceberg?. Intern Med J. 2006;36(3):197-199. Available from: https://doi.org/10.1111/j.1445-5994.2006.01039.x.
[7] World Health Organization. WHO standards for prosthetics and orthotics. 2017. Available from: https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/.

one lower-limb amputation than non-diabetic patients[8] and WHO estimates that incidence of diabetes will rise from 415 million in 2015 to 642 million in 2040. The global P&O need is estimated to increase from 0.5% of the global population to 1% of the population by 2050.[7]

FIGURE 2: REGIONAL DISTRIBUTION OF PEOPLE LIVING WITH AMPUTATION (2017)[9]



3.2 Use of prosthetic devices improves quality of life and reduces mortality, but only 5-15% of people in LMICs that need one have access.

Appropriate selection of prosthetic devices can improve user quality of life and reduce mortality. Prosthetic use allows amputees to regain mobility and independence. For example, 80% of amputees in Vietnam and India who had received functioning prostheses described themselves as employed.[10,11] This permits reintegration into work and community, raising quality of life measures such as well-being, productivity, intimacy, health, and safety.[12,13] In addition to improvements in their quality of life, a recent study in the US suggests that prosthetic users have greater life expectancy following amputation, and 12-month mortality rates are two times lower compared to non-users with similar disease and demographic profiles, though this study does not control for the prevalence of co-morbidities.[14] From a financial perspective, access to appropriate prosthetic devices decreases the need for hospitalisation and associated acute care, resulting in reduction of health expenditure. In the US Medicare system, the cost of providing prosthetic devices was found to be fully amortised within 12 to 15 months due to a reduction of care in other settings.[15]

Although clinical, economic and social benefits of prosthetic use are documented in HICs, there is limited evidence to draw conclusions in LMICs, resulting in low prioritisation and investment by governments.

[8] Johannesson A, Larsson G, Ramstrand N, Turkiewicz A, Wirehn A, Atroshi I. Incidence of lower limb amputation in the diabetic and nondiabetic general population: a 10-year population-based cohort study of initial unilateral and contralateral amputations and reamputations. Diabetes Care. 2008;32(2):275-280. Available from: https://doi.org/10.2337/dc08-1639.

[9] McDonald CL, Westcott-McCoy S, Weaver MR, Haagsma J, Kartin, D. Global prevalence of traumatic non-fatal major limb amputation. Prosthet Orthot Int. Submitted 2020 March.

[10] Matsen S. A closer look at amputees in Vietnam: A field survey of Vietnamese using prostheses. Prosthet Orthot Int. 1999;23(2):93-101. Available from: https://doi.org/10.3109/03093649909071619.

[11] Adalarasu, K, Jagannath M, Mathur MK. Comparison on Jaipur, SACH and Madras Foot: A psychophysiological study. International Journal of Advanced Engineering Sciences & Technologies. 2011;4(1), 187-192. Available from: https://www.doc-developpement-durable.org/file/sante-hygiene-medecine/handicaps/Protheses-Propylene/5.IJAEST-Vol-No-6-Issue-No-2-Comparison-on-Jaipur,-SACH-and-Madras-Foot-187-192.pdf.

[12] Powell B, Mercer S, Harte C. Measuring the impact of rehabilitation services on the quality of life of disabled people in Cambodia. Disasters. 2002;26(2):175-191. Available from: https://doi.org/10.1111/1467-7717.00199.

[13] Adegoke B, Kehinde A, Akosile C, Oyeyemi A. Quality of life of Nigerians with unilateral lower limb amputation. Disability, CBR & Inclusive Development. 2013;23(4). Available from: https://doi.org/10.5463/dcid.v23i4.192.

[14] Dobson, A, El-Ghamil, A, Shimer, M, DaVanzo, J. Retrospective cohort study of the economic value of orthotic & prosthetic services among medicare beneficiaries. American Orthotic & Prosthetic Association; 2013. Available from: https://www.aopanet.org/wp-content/uploads/2014/01/Dobson-Davanzo-Report.pdf.

[15] Dobson A, Murray K, Manolov N, DaVanzo J. Economic value of orthotic and prosthetic services among medicare beneficiaries: a claims-based retrospective cohort study, 2011–2014. J Neuroeng Rehabil. 2018;15(S1). Available from: https://doi.org/10.1186/s12984-018-0406-7.

Limited data in LMICs on the number of amputees, need for prosthetics, current coverage of prosthetic use, and the clinical benefits and economic returns, make it difficult for policy-makers to ascertain the economic and health burden, and to make appropriate budget allocations. Measuring the cost-effectiveness of prosthetic provisioning through the reduction of the cost of care in other settings or in contribution to the economy over time would drive increased awareness, attention, and urgency.

WHO estimates that prosthetics coverage in LMICs is only 5-15%. Although these numbers are not based on comprehensive data, it indicates the low coverage in LMICs when compared to HICs. In Indonesia, for example, an estimated 4 million people need P&O services, with 146,000 amputees.[16] However, only around 3,000 users (2% of amputees) have been fitted.[17] In the US, on the other hand, 86% of lower-limb amputees adopt prosthetic devices.[18] Additionally, individuals will need multiple devices in their lifetime.

3.3 Prosthetic devices are available across a spectrum of materials and technologies and are customised based on needs of the user.

Prosthetic devices are classified by the body part(s) they replace (Table 1) and their construction. Lower-limb prosthetic devices are divided into several types, including: transfemoral (TF) or above-knee prostheses, transtibial (TT) or below-knee prostheses, and partial foot and toe prostheses that are used for amputations of the toe and foot. Exoskeletal (also referred to as conventional) prostheses have external walls that provide shape to the device and also perform the weight-bearing function. They are usually manufactured from one piece of raw material and have limited adjustability and customisability. In endoskeletal (also referred to as modular) prostheses, weight is transmitted through a central shank from socket to foot and to the ground.[19] These are composed of multiple components, each of which serve different functions, and can be mass-produced and then selected, assembled, and adjusted to adapt to a user's lifestyle (Table 2).

Prosthetic devices are customised and fitted based on the needs of each user. Prosthetic sockets have a high level of customisation since they serve as the interface between the prosthesis and the user. They are individually fabricated after patient assessment and measurement, and take into consideration the amputation, anatomy, and any underlying medical conditions to ensure comfort and fit. Prosthetic components are also selected and customised to account for the measurements and lifestyle of the user. Users in LMICs often require their P&O devices to function for a range of environmental and lifestyle factors, such as activity (agricultural or labouring livelihoods), temperature, humidity (requiring waterproof or anti-rust features), culture (being able to sit cross-legged or to squat; colouring of limb coverings or cosmesis), and affordability. Poorly-fitted or low-functionality prosthetic solutions that do not meet users' needs often lead to abandonment.

TABLE 1: TYPES OF PROSTHETIC DEVICES

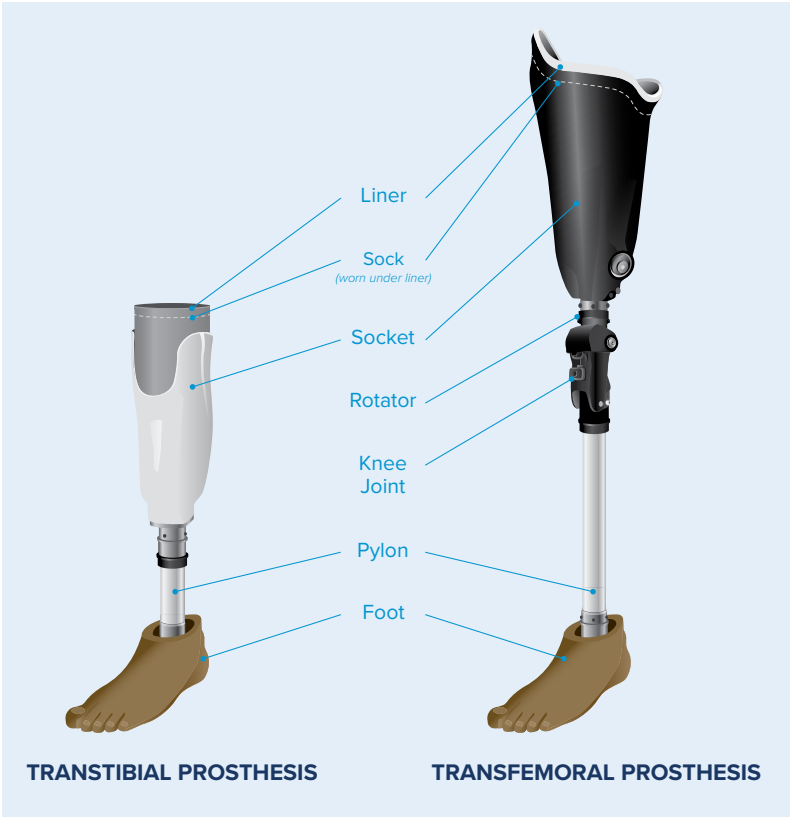
UPPER LIMB TYPES	BODY PART(S) REPLACED
Shoulder	Shoulder, elbow, forearm, wrist, hand
Transhumeral (TH) *(above elbow)*	Elbow, forearm, wrist, hand
Transradial (TR) *(below elbow)*	Wrist, hand

LOWER LIMB TYPES	BODY PART(S) REPLACED
Transfemoral (TF) *(above knee)*	Knee, shin, ankle, foot
Transtibial (TT) *(below knee)*	Ankle, foot
Partial foot (PF)	Part of the foot

[16] Indonesia Basic Health Research, Riskesdas. 2018.
[17] CHAI expert consultation.
[18] Boston Consulting Group. 2017. Global Prosthetics Market.
[19] Hanger Clinic. Lower limb extremity componentry [Internet]. Hanger; 2020. Available from: http://www.hangerclinic.com/limb-loss/adult-lower-extremity/Pages/Lower-Extremity-Componentry.aspx.

TABLE 2: COMPONENTS OF MODULAR (ENDOSKELETAL) LOWER LIMB PROSTHETIC DEVICES

A prosthesis is typically assembled from the following components: 1) liners: soft material that ensure fit and comfort; 2) socket: interface between the residual limb and the prosthesis; 3) terminal device: the foot; 4) joints: knee, ankle; 5) pylon: allows adjustment of the length of the prosthesis. The device is attached to the body using a suspension system: these range from straps or leather to pin and lock. In a modular prosthetic device, the socket is usually made to order from raw materials while the other components can be manufactured centrally and then customised, based on selection of size or adjustments to fit the users.



COMPONENT	DESCRIPTION	RANGE OF RAW MATERIALS
Liner, sleeves, socks	Soft interface materials that ensure fit, comfort, and that the prostheses stays attached to residual limb. Certain suspension systems require use of liners. When used properly, they provide a cushioning effect within the socket, help to minimise friction forces, and provide even pressure distribution. Socks can be used to adapt to changes in the volume of the residual limb.	Ethylene-vinyl acetate (EVA) foam, silicone, gel, urethane, thermoplastic elastomer (TPE), pelite, wool, cotton.
Socket	Where the prosthetic device attaches to the residual limb. Because the residual limb is not meant to bear body weight, sockets must be individually moulded and meticulously fitted to ensure pressure is distributed, and to avoid damage to skin and tissue.	Polypropylene, thermoplastic elastomer (TPE), wood, aluminium, glass-reinforced plastic (GRP), resin, carbon fibre.
Knee joint	Mimics the function of a natural knee by providing safety, symmetry, and smooth movement while walking. High variations exist in activity level, functionality, technology, and materials.	Titanium, aluminium, polypropylene, nylon, wood.
Pylon	Connects the socket to the foot. Lightweight and absorbs shock.	Wood, titanium, aluminium, steel, carbon fibre, glass-reinforced plastic (GRP), polypropylene.
Foot	Designed to be the point of contact between prosthesis and contact surface, with different foot designs optimised for different functions or terrains.	Polypropylene, polyurethane, wood, rubber, carbon-fibre.
Cosmesis	Limb covering to mimic appearance of real limb. Can be readymade or custom-designed, or made from locally sourced materials.	Silicone, local fabrics, Ethylene-vinyl acetate (EVA) foam.

Prosthetic components can be made from a wide range of materials which affect the durability, functionality, and price of the device. Materials that are commonly used in LMICs, because of price and availability, include wood, leather, rubber, aluminium, and polypropylene. These materials create affordable devices, albeit with limited flexibility and suitability for different use cases. Advanced materials such as carbon fibre and titanium are more expensive, but offer increased functionality, flexibility, and durability and are typically lighter in weight. Material and component selection may impact whether the user is able to participate fully in their desired daily activities, and whether the user continues to wear the device over time.

Prosthetic components are available in a range of basic to advanced technologies that affect functionality and control. Prostheses built with basic mechanical components, which usually cost up to USD 2,000, are user-controlled and have a limited range of movement and functionality, particularly in the knee and ankle. More advanced components, which cost up to USD 15,000, allow for a wider range of motion and incorporate pneumatic or hydraulic control systems, resulting in a more natural gait. Devices that use microprocessors and other intelligent response controls that can sense the users' activity level, gait, and environmental changes to control the limb, and cost up to USD 70,000. These high-technology prostheses are usually customised to the user's desired lifestyle and are comfortable, lightweight, and feel like a real limb to users. On the other hand, exoskeletal prostheses that are typically manufactured from one raw material can be priced as low as USD 100-USD 500. See Figure 3 for examples of lower-limb prosthetic devices.

FIGURE 3: EXAMPLES OF LOWER-LIMB PROSTHETIC DEVICES

CONVENTIONAL (EXOSKELETAL)[20]	BASIC MODULAR (ENDOSKELETAL)[21]	ADVANCED MODULAR INCLUDES HYDRAULIC, PNEUMATIC, OR MICROPROCESSOR CONTROLS[22]
 TerraPhoto-Shutterstock	 Andrew Mayovskyy/Shutterstock	 Ottobock
Made from one type of raw material, with limited customisation or variation of components.	Mechanical user-powered components made from aluminium, steel, or rubber, amongst others. Modular design permits customisation and selection of components to suit user needs.	Advanced functional components made from lightweight materials designed for comfort and activity (carbon fibre, titanium). Some advanced joints employ hydraulic or pneumatic joints for smooth gait control. Others utilise microprocessors equipped with intelligent controls and sensors that respond to the user and environment. Though designed to be durable, most advanced components often have limited lifespans in LMIC environments.

[20] TerraPhoto. Shutterstock. Exoskeletor lower limb. Royalty Free ID: 154713758
[21] Matammana Orthopedic Suppliers Company. Lower extremity prosthetics and orthotics [Internet]. 2020. Available from: http://www.orthopedic.lk/?p=lower_extremity.
[22] Ottobock. Knee joint C-Leg [Internet]. 2013. Available from: https://www.ottobock.com.tr/en/prosthetics/lower-limb/solution-overview/knee-joint-c-leg/.

3.4 WHO and the International Society for Prosthetics and Orthotics (ISPO) have issued standards for the provision of appropriate prosthetic and orthotic services, which requires specialised health professionals, infrastructure, equipment, and supply chains.

In 2017, WHO, in partnership with ISPO and the United States Agency for International Development (USAID), published *Standards for Prosthetics and Orthotics*, a two-part standards and implementation manual for health systems providing P&O services.[23] The standards outline recommendations to countries on appropriate policy, products, personnel, and service provision in establishing a P&O services system (Figure 4). Regarding the selection of prosthetic components, the standards highlight the following key considerations:

- **USER:** level of amputation, clinical presentation of the residual limb, age, general health, weight, strength, desired mobility level, type of work, and lifestyle.
- **CONTEXT:** environment (terrain, temperature, humidity), proximity to service providers for maintenance, availability of local or imported materials and components, types of fabrication equipment, and component supply available to the service provider.
- **FINANCING:** availability of reimbursements and eligibility of various component types, price of components, longevity of components, and need for replacement.

FIGURE 4: 4-STEP PROSTHETIC SERVICE DELIVERY PROCESS

1. Assessment	The prosthetist evaluates patient health, lifestyle, environment, and amputation to prescribe an appropriate prosthetic solution (including selection of appropriate components and materials to match user needs).
2. Fabrication & Fitting	The prosthetist takes measurements and casts impressions of residual limb. The cast of the stump is modified by the clinician to take into account individual biomechanics and attributes. The prosthetist, in collaboration with prosthetic technicians, fabricates the socket and assembles components. Finally, the prosthetist fits and customises the prosthesis to the user's needs.
3. User Training	User undergoes physical therapy and functional training to maximise benefits, ensure safety, and continued use. Physical therapist coaches user in gait training, and provides education on appropriate maintenance and care after the device is provided.
4. Product Delivery & Follow-up	When the prosthesis is optimally fitted, the prosthetist conducts requisite quality and functionality checks, and delivers the prosthesis. Follow-ups with the patient tracks outcomes and troubleshoots issues that may arise after a period of use and are an important feedback loop. For new amputees, regular socket fit assessment is needed as changes can occur as stump consolidation takes place.

[23] World Health Organization. WHO standards for prosthetics and orthotics. 2017. Available from: https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/.

Prosthetic service units that provide prosthetic services can be expensive to set up, and require specialised infrastructure and equipment. Different types of equipment and machinery, such as an oven, vacuum suction and drills, are utilised to fabricate the socket that is moulded to the residual limb of the patient and to assemble the prosthesis. In addition, other workshop areas are also required to ensure appropriate services (see Figure 5). The estimated cost of establishing a prosthetic service unit in a LMIC ranges from USD 200,000[24] up to USD 400,000[25] with machinery accounting for 50-80% of the cost.

FIGURE 5: PROSTHETICS AND ORTHOTICS SERVICE UNIT REQUIREMENTS[26]

Space requirements	A Prosthetics and orthotics unit has 4 main areas: 1. Reception/waiting Area 2. Clinical area 3. Workshop area (typically multiple rooms and workbenches) 4. Personnel area
Types of equipment & machinery	• Patient assessment tools, casting tools, and materials • Mould modification equipment: hand drills, sanding equipment, hand tools • Socket casting equipment: oven, vacuum suction • Socket modification & assembly equipment: router, heavy-duty stand drills, vices and clamps, saws • Physical therapy equipment: parallel bars, steps, ramps, cushions • Furniture for non-workshop areas • Workbenches, storage equipment for raw materials and components • Computer for administration, inventory, and patient management

3.5 Trained and accredited prosthetists/orthotists are critical to the service delivery process.

Prosthetists/orthotists assess, fabricate, and fit users with P&O devices. They undergo specialised education and training which equip them to assess and educate the user, prescribe the appropriate device, fabricate the custom-fitted components, and to fit the final device. ISPO and WHO have developed guidelines for the training of prosthetists/orthotists[27] which include the delineation of tasks of the various personnel and guidelines for their training. In 2018, ISPO published the new *ISPO Education standards for prosthetics/orthotics occupations*[28] and updated the three levels of professional designations (see Table 3): Prosthetists/Orthotists, Associate Prosthetists/Orthotists and Prosthetics/Orthotics Technicians. Prosthetists/Orthotists and Associate Prosthetists/Orthotists are referred to as clinicians, who mainly perform clinical work, while Prosthetics/Orthotics Technicians are referred to as non-clinicians. Over the years, ISPO has implemented an accreditation process for training programmes to professionalise the role of the prosthetist/orthotist internationally. Among the worldwide training institutions, there are 17 P&O schools which offer ISPO-accredited training in LMICs, of which 5 offer training at Prosthetist/Orthotist level, 13 at Associate Prosthetist/Orthotist level and 1 at Prosthetic/Orthotic Technician level.

[24] Cost estimates for establishing a P&O service unit in Myanmar. 2019.
[25] CHAI Draft prosthetics services costing analysis. 2019.
[26] World Health Organization. WHO standards for prosthetics and orthotics. 2017. Available from: https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/.
[27] World Health Organization. Guidelines for training personnel in developing countries for prosthetics and orthotics. 2005. Available from: https://apps.who.int/iris/handle/10665/43127.
[28] International Society for Prosthetics & Orthotics. ISPO education standards for prosthetic/orthotic occupations. 2018. Available from: https://cdn.ymaws.com/www.ispoint.org/resource/resmgr/3_learn/ispo_standards_nov2018_sprea.pdf.

There are also a number of non-ISPO-accredited training institutes in operation in LMICs, with varying levels of effectiveness in graduating practitioners with adequate skills to deliver quality services. Training prosthetists to ISPO standards has shown to positively impact developing new service capacity, appropriateness of prosthetic and orthotic service delivery, clinical leadership, and driving development in professional communities in both HICs and LMICs[29] (see Case Study 1).

TABLE 3: DESIGNATIONS IN PROSTHETIC AND ORTHOTIC PROFESSIONS ACCORDING TO 2018 EDUCATION STANDARDS (SEE ANNEX B FOR DETAILED DESCRIPTIONS)[30,31]

PROFESSIONAL DESIGNATION	RESPONSIBILITIES	TRAINING	RECOMMENDED NUMBER
CLINICIANS			
Prosthetist/Orthotist *Formerly: Category I Prosthetist/ Orthotist*	• **CLINICAL:** assessment, prescription, fitting, design, fabrication, monitoring outcomes. • **NON-CLINICAL:** leadership of clinical team, management of service unit, training, education, community demonstrations, awareness-building.	4 years full-time at university level.	5-10 clinicians per million population, Each service point should have at least one Prosthetist/ Orthotist or experienced Associate Prosthetist/ Orthotist.
Associate Prosthetist/ Orthotist *Formerly: Category II Orthopedic Technologist*	• **CLINICAL:** clinical assessment, prescription, technical design, fabrication, fitting of device, monitoring outcomes.	3 years formal structured.	
NON-CLINICIANS			
Prosthetist/Orthotist Technician *Formerly: Category III Prosthetic/Orthotic Technician/Bench Worker*	• **NON-CLINICAL:** support (Associate) Prosthetist/Orthotist in device fabrication, assembly, maintenance, repair. Not involved in direct services to the user.	2 years formal structured or 4 years on the job/ in-house training.	2 non-clinicians per clinician.

Besides prosthetists and orthotists, multidisciplinary teams that include physical therapists and occupational therapists are critical for pre-fitting and post-fitting rehabilitation. Without rehabilitation and physical therapy, users may abandon their prosthesis due to discomfort or safety issues. These auxiliary rehabilitation clinicians also offer opportunities to provide gait training or physical therapy outside a service unit setting, since they are often integrated with health services. In some settings, rehabilitation clinicians are also trained to provide device maintenance or repairs.

[29] Sexton, S. Prosthetic & orthotics impact assessment. International Society for Prosthetics & Orthotics; 2012. Available from: https://cdn.ymaws.com/www.ispoint.org/resource/resmgr/4_EXCHANGE/ispo_impact_assessment_tatco.pdf.

[30] International Society for Prosthetics & Orthotics. ISPO education standards for prosthetic/orthotic occupations. 2018. Available from: https://cdn.ymaws.com/www.ispoint.org/resource/resmgr/3_learn/ispo_standards_nov2018_sprea.pdf.

[31] In 2005, ISPO and WHO defined the professional designations of prosthetics and orthotics workforce in the *Guidelines for Training Personnel in Developing Countries for P&O. In 2018, ISPO updated the professional designations in ISPO Education Standards for Prosthetic/Orthotic Occupations* due to confusion caused by the categories used in previous nomenclature. Both systems are widely referred to in the industry.

CASE STUDY 1: PROSTHETIST/ORTHOTIST TRAINING CENTRES IN SOUTHEAST ASIA AND EAST AFRICA

Southeast Asia: Cambodian School of Prosthetics and Orthotics (CSPO)

CSPO was established in 1994 in collaboration with the Cambodian Ministry of Social Affairs to address the shortage of trained prosthetists/orthotists in Cambodia and across Southeast Asia. CSPO is currently upgrading its accreditation by ISPO to provide prosthetist/orthotist degree training and has been accredited since 1998 for Associate Prosthetist/Orthotist diploma and Prosthetics/Orthotic Technician training. It was the first ISPO-accredited school to receive ISO 9001 Quality Management System accreditation, exhibiting international levels of production quality control. Since establishment, 327 individuals from 27 countries across the region and beyond have graduated from the school and entered the profession.

The establishment of the school led to quality improvements in P&O services across Southeast Asia. Having local training capacity led to the expansion of services and developed a cadre of professionals and leaders who rapidly transformed the quality of P&O services in the region. CSPO curriculum and graduates have been used worldwide by Exceed to seed P&O training institutes in Sri Lanka, Indonesia, the Philippines, and Myanmar. CSPO has developed the domestic capacity of prosthetists/orthotists, enabling workforce nationalisation (instead of reliance on expatriate practitioners) across numerous countries, and established professional associations who advocate for recognition of the profession and policy changes to improve service capacity.

Anchored by CSPO, a P&O ecosystem has evolved in Cambodia. The ecosystem includes a social enterprise that provides differentiated services for users at different income levels, and is part of a regional component manufacturing and distribution company which also operates using a social enterprise model.

Despite this progress, the impact is limited by poor referral rates and awareness of prosthetic services. Limited professional development and recognition of the prosthetist/orthotist profession also leads to attrition and inequity for users outside urban areas.

East Africa: Tanzania Training Centre for Orthopaedic Technologists (TATCOT)

TATCOT was founded in 1981 with the support of German Technical Cooperation (now Gesellschaft für Internationale Zusammenarbeit) and operates under the Directorate of Human Resources Development for the Ministry of Health of Tanzania. TATCOT offers ISPO-accredited degrees and diplomas. As of December 2017, 752 students have graduated: 134 Prosthetists/Orthotists and 370 Associate Prosthetists/Orthotists, the remainder being specialised technicians. Graduates stem from 43 countries, including 32 in Africa.

Prosthetist/Orthotist and Associate Prosthetist/Orthotist degrees at TATCOT cost USD 44,500 and USD 25,725 respectively.[32] TATCOT offers a Blended Learning Education programme that can allow Associate Prosthetist/Orthotist diploma holders to upgrade to a Prosthetist/Orthotist degree while continuing to work on the job. The curriculum combines online lectures with on-site practical teaching. TATCOT is continuing to experiment with blended learning to provide continuing education as well as specialisation training.

A 2012 USAID-funded assessment showed that TATCOT graduates have had lasting impact across East Africa. In Tanzania, Kenya, and Uganda, graduates have improved quality of care, established outreach services and mentorship, and established professional communities that enable professional development.

In addition to being a leading training institute, TATCOT is a provider of P&O services in Tanzania. A barrier to providing affordable services is the high cost of materials and components, most of which need to be imported. To address this, TATCOT has worked with professional associations in Tanzania to advocate for the inclusion of P&O components in central procurement processes by the Ministry of Health for the national Medical Store.

[32] Tanzania Training Centre for Orthopaedic Technologists. Prosthetics & orthotics - Bachelor of Science (BSc) [Internet]. 2018. Available from: www.tatcot.org/course_po_bsc.html.

3.6 Donor funding is limited, with support mainly focused on training prosthetists/orthotists and establishing service provision capacity.

Donor funding in the prosthetics sector has historically been prioritised for the training of prosthetists/orthotists to ISPO-accredited levels. Nippon Foundation and USAID have been the leading donors to support the establishment of ISPO-accredited schools. Building on the success of CSPO, between 2003-2020, Nippon Foundation invested around USD 55 million for the expansion and establishment of schools in the Philippines, Indonesia, Thailand, and Myanmar in collaboration with their governments and implemented by Exceed Worldwide. These schools have graduated 600 practitioners as of December 2018. While some training institutes are established and staffed by international organisations, and transitioned to local practitioners over time (see CSPO in Case Study 1), others, such as the Sirindhorn School of Prosthetics and Orthotics, are founded with government ownership and local workforce from the start. Training institutes in LMICs are typically established with funding from donor organisations. Since the mid-1990s, USAID has supported the development of the prosthetist/orthotist workforce by funding the development of regional ISPO-accredited schools and scholarships for training personnel from 34 different countries. Additionally, through the Leahy War Victims Fund, USAID has invested in the development of the WHO Standard for Prosthetics and Orthotics Services, and established P&O services and service units in LMICs since 1989.

Other large contributors operate primarily in the humanitarian response field, such as the International Committee of the Red Cross (ICRC), Humanity & Inclusion (HI) and Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS). These organisations primarily focus on supporting the expansion of service provision capacity and also run large rehabilitation programmes, and will therefore be discussed in detail later in this document.

4. Market Assessment

4.1 The global prosthetic components market is estimated at USD 1.3 billion and dominated by a few companies that primarily focus on HIC markets; however, lower-cost suppliers are emerging.

The global prosthetic components market is valued at USD 1.3 billion and growing +3% every year.[33] The US and Germany are the largest markets in the world by value. China is the largest market by volume, followed by the US and India. HIC markets can be characterised as high-value and low-volume, which is primarily driven by higher pricing of components and the selection of more advanced technologies. Regarding component type, microprocessor joints are estimated to account for more than 50% of global market value, while mechanical feet account for 60% of global volume. India and Brazil are the fastest-growing markets. The highest growth segments are high-tech components, including myoelectric hands and microprocessor feet.

A few companies dominate the global market, with varying presence in LMICs (see Annex C). Ottobock (Germany) is the leading global supplier of modular components. Founded post-World War I, the company has achieved a strong market position by leading innovation and establishing networks of prosthetics clinics. Ottobock is present in LMICs through distributors and service providers, as well as through acquisitions or technology transfer partnerships. Össur (Iceland) is the second-largest leading supplier, estimated to be half the size of Ottobock. Össur has regional presence in Europe, the Middle East, Southern Africa, and the Americas, with sales growing fastest in the Asia-Pacific region. Proteor (France) and Blatchford (UK) are long-standing companies who focus on HIC markets, but have also developed low-cost, basic solutions targeted towards LMICs. Proteor components are commonly found in Francophone Africa, partially through partnerships with HI, with whom they have developed an emergency prosthetic kit. Blatchford has formed the Endolite subsidiary and line of prosthetics, which targets large LMIC markets such as China and India.

Prices for different prosthetic devices can vary considerably, depending on the brand, country of origin, technology, and materials. Basic mechanical TF limbs are typically sold by the leading companies for between USD 1,000 and USD 3,000. Manufacturers from China, India, Turkey, Russia, and Taiwan have emerged offering lower-priced limbs, ranging from USD 100 to USD 500. In addition, some start-up companies have developed specific components suited for a LMIC context, such as D-Rev's ReMotion Knee (USD 80) as well as the LegWorks All-Terrain Knee (USD 200). Select prosthetic solutions can be found in Annex D. Many of these alternative suppliers have obtained internationally-recognised certificates of quality, such as approval by the US Food and Drug Administration (FDA) and the European Commission (CE marking), report conformity to ISO standards, and operate in LMICs.

4.2 LMIC markets for prosthetic devices are small as they lack capacity for provision.

Lack of prioritisation of investment and coordination by LMIC governments limits the provision of prosthetics and growth of a market. LMIC governments have largely not prioritised investments because they lack awareness of the unmet need and value of providing prosthetic services. Further investigations to quantify the return on investment of providing prosthetic services is needed to advocate for prioritisation and investment. Additionally, prosthetic services and rehabilitation often fall within the responsibility of multiple ministries, requiring coordination of investments between various groups, such as the Ministries of Health, Social Welfare, Labour, Education and Veteran Affairs, which is often lacking.

[33] Össur Investor Relations. Our markets [Internet]. Available from: https://corporate.ossur.com/corporate/investor-relations/our-business/our-markets.

Developing sustainable markets for prosthetic services requires long-term planning and investment in developing service capacity. In LMICs, the high cost of establishing and operating a prosthetic service unit has limited the number of access points, which are often only found in tertiary-level teaching hospitals in capital cities or urban centres. The lack of service points presents a logistical and financial barrier to many users who must travel long distances. Expansion of service points requires an increased capacity of accredited prosthetists/orthotists. Training for ISPO-accredited professional designations often requires sponsorship and travel to a regional school. Once trained, it is proving challenging to retain prosthetists/orthotists in the country due to poor working conditions, lack of professional recognition, and the ability for accredited personnel to seek employment in the private sector or abroad. Due to the shortage of required capacity in LMICs, personnel will sometimes take on responsibilities above their level of training.

TABLE 4: CAPACITY GAP OF P&O SERVICE UNITS AND PERSONNEL IN SELECT LMICS[34]

COUNTRY (population)	NUMBER OF P&O SERVICE UNITS		P&O PERSONNEL		
	NEED	ACTUAL	NEED	ACTUAL	STATUS OF IN-COUNTRY TRAINING INSTITUTION
Kenya (50 million)	50-150	40[35]	250-500	200 trained personnel, very few ISPO-accredited.	Not ISPO-Accredited.
Rwanda (12 million)	12-36	14 (both public and private sector)	120-240	67 ISPO-accredited clinicians: 53 Associate Prosthetists/Orthotists and 14 Prosthetists/Orthotists.	Accredited by ISPO.
Indonesia (260 million)	260-780	24 in general hospitals[36]	1,300-2,600	243 accredited clinicians.	Accredited by ISPO.

Though government financing may exist in some LMICs, current reimbursements for prosthetic services and devices are largely insufficient. Table 5 compares reimbursements available and the associated prices of prosthetics in select LMICs. The prices do not consider indirect costs typically incurred by the user relating to travel or accommodation, etc. In addition, amputees may have already spent available financial resources on upstream medical treatments that led to and include the amputation, particularly if those services are also not covered through the public health system. To build upon the efforts countries have made to date to offer coverage, additional analysis of the cost to users and the value of providing prosthetic services is needed to build momentum for increased support.

[34] World Health Organization. WHO standards for prosthetics and orthotics. 2017. Available from: https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/.
[35] CHAI expert consultation.
[36] CHAI expert consultation.

TABLE 5: INSURANCE AND REIMBURSEMENT RATES FOR AMPUTEES FOR LOWER-LIMB PROSTHETIC DEVICES

COUNTRY	FINANCING FOR USERS	ELIGIBILITY CRITERIA	PRICE (USD)
Kenya	National Health Insurance Fund: provides reimbursement, up to a job-dependent annual maximum.	Must be civil or public servants. Pre-approval is required.	TT: USD 500 TF: USD 1,000
Rwanda	Community-Based Health Insurance: used by 85% of Rwandans; does not generally cover prosthetic devices except at 2 university teaching hospitals.	Beneficiaries can access up to RWF 175,000 (USD 175) at university teaching hospitals in Rwanda, which typically covers the cost of a prosthetic foot.	TT: USD 360-1,000 TF: USD 600-1,000
	Rwanda Social Security Board: covers 85% of cost of device and services.	Only civil servants; requires 15% employee salary contribution.	
	Military Medical Insurance: covers 85% of cost of device and services.	Only members of Rwanda Defence Force and police staff.	
Indonesia	National Health Insurance: covers services, but prosthetic device coverage is Rp 2.5 million (USD 180) every 5 years.	Requires a prescription; can only be accessed through a government secondary healthcare facility.	TT: USD 920 TF: USD 1,700
	Other financial coverage is available for people under social welfare from certain provinces.		

Novel financing mechanism for users, such as micro-loans and leases from financial institutions, could increase affordability of prosthetic services, but have not yet been demonstrated or piloted. Since prosthetic devices enable many users to return to work, there is an economic argument to be made for lenders. No such options exist in LMICs today. Establishing funds to provide loans to amputees or assisting financial institutions to understand the risk profile of lending to amputees can unlock user ability to afford prosthetic devices.

4.3 Lack of LMIC government investments has left a gap that has been filled by non-governmental (NGOs) and faith-based organisations (FBOs).

NGOs and FBOs provide and support prosthetic services in LMICs. These organisations primarily initiate programmes in response to conflict, natural disasters, or humanitarian crises. They provide technical assistance, train clinicians, and establish supply channels. While NGOs and FBOs typically work in partnership with governments, their individual deployment models result in parallel systems for provisioning, procurement, supply, and user engagement. Governments become reliant on the funds and technical inputs. Ownership and operations have been transferred to the local governments with varying levels of success.

ICRC, BMVSS and HI are the largest international organisation and NGO providers in LMICs. ICRC and HI support a broad network of rehabilitation service points in over 40 LMICs, and BMVSS is primarily focused on India. ICRC and BMVSS each deliver around 25,000 prosthetic devices every year, while HI delivers around 6,000 devices. They play a critical role in helping to fill the gap in prosthetic services in LMICs. More information can be found in Annex E on these providers.

ICRC and BMVSS have developed products for low-resource settings. These products are consistent in design and fabrication, which allows for streamlined centralised manufacturing to achieve lower costs and simplified provisioning. The availability of these products has been impactful, particularly in conflict and

emergency situations. However, these products provide limited customisability for different user lifestyles and activity levels. ICRC's polypropylene prosthetic technology is widely accepted and recognised because of its suitability for deployment in LMIC contexts. Since 2019, ICRC has switched to Alfaset, a non-profit arm of Swiss-based manufacturer Rehab Impulse. In contrast, studies suggest that BMVSS's Jaipur solutions are poorly accepted due to high failure rates and low durability, resulting in low adherence and lack of technical and clinical acceptability.[37]

Beyond these three international organisations, additional NGO and FBOs are listed in Annex F.

4.4 Collaborations between the public sector and for-profit organisations may have the potential to mobilise cross-sector investments to expand access.

Coordinating investments between the public and for-profit sector could drive expansion of services. In the absence of government-funded services, a for-profit sector has emerged which caters mostly to populations who can afford to pay out of pocket. Private providers offer a variety of prosthetic solutions, varying in functionality, quality, and pricing. Quality can be a challenge in the private sector because of a lack of regulatory oversight or frameworks. Private-public partnerships (PPP) and other mechanisms that integrate the public sector and for-profit models can allow governments and private sector providers to collaborate, co-invest, and integrate resources to jointly expand services while ensuring quality. Demonstration and pilot projects are underway in LMICs (see Case Studies 2 and 3). These models rely on willing government partners, appropriate policies (i.e. reimbursement, quality control) that regulate and enable private-sector investments, and could be further expanded through enabling the private sector to achieve financial sustainability.

CASE STUDY 2: PUBLIC-PRIVATE PARTNERSHIP IN THAILAND

Mahidol University is a public-sector institution that hosted the first ISPO Category I-accredited school in Southeast Asia. Scandinavian Orthopaedic Laboratory (SOL) is a private sector enterprise in Sweden. Together, the two partners collaborated in 2017 to create the Centre of Excellence for Prosthetics and Orthotics (CEPO) to pilot PPPs as a new way to co-invest in P&O services.

In the past, public service units offered basic services and products free of charge, covered by national insurance schemes. Issues in this public system included low quality of services and devices, and long wait times. At a price premium, private providers offered a higher level of service and higher-priced component options in well-equipped facilities with well-trained staff. To provide an alternative to the public and private sector service levels, CEPO was established to serve a middle class who want to access government reimbursement for prosthetic services, but also have a desire for faster access to services and better quality components, and can afford to supplement public insurance funding. CEPO also provides clinical training for P&O staff and other rehabilitation professions.

Partners share investments and costs, and assume profits and losses equally. Mahidol University invested in the construction of the site, employs all local staff, and offers existing hospital administration systems for patient records and payments. SOL invested in the equipment, furniture, and machinery required to achieve high level of service. SOL also employs management staff and manages procurements, since procurement restrictions prevent the government entity from selecting from a range of appropriate products.

CEPO has set a new standard for quality of P&O services through improved service unit management and leadership, and increased quality of components. As a result, clinicians and users have begun to request access to better-quality products and services in other public sector service units. While profitability has not yet been achieved after 3 years, CEPO anticipates it will soon be profitable as volumes increase through broader awareness and improved referrals. Moving forward, access to a lower cost of capital for establishment could encourage additional private sector investments in service expansion and to shorten the time to reach financial sustainability.

[37] Jensen J, Craig J, Mtalo L, Zelaya C. Clinical field follow-up of high density polyethylene (HDPE)-Jaipur prosthetic technology for trans-femoral amputees. Prosthetics and Orthotics International. 2004;28(2):152-166. Available from: https://doi.org/10.1080/03093640408726700.

CASE STUDY 3: EXCEED SOCIAL ENTERPRISE

Exceed Worldwide is a UK-based non-profit that has established five P&O schools in Southeast Asia and supports the capacity development to train prosthetists/orthotists in the region. Exceed also supports local prosthetic services and runs a social enterprise which provides differentiated services to users of different income levels. By applying a government-recognised poverty assessment tool in Cambodia, clients with suitable financial means are offered services and products which command a higher price and profit, while low-income users are able to access quality services free of charge and products at cost-recovery price. The services for low-income users are supported by the government and by the People with Disability Foundation.

The social enterprise also operates a regional distribution company, which procures materials and components from international and local suppliers in order to supply service providers across Southeast Asia. All profits support philanthropic activities such as subsidised products and services for low-income users and scholarships for training prosthetists/orthotists. Since its initial launch in Cambodia, Exceed has expanded this model to Sri Lanka and the Philippines. The social enterprise is currently supported by Innovate UK and researching similar models in Myanmar.

4.5 Collecting amputee data supports improved advocacy to drive investment in prosthetic services and improvements to quality of care.

Amputee data is the starting point to drive awareness and prioritisation in prosthetic services; however, very limited data is currently collected in LMICs. Investments in collecting such data and developing registries help to illuminate the full need and monitor amputee outcomes. Data initiatives in LMICs include examples such as ASCENT (see Case Study 4) and ICRC's Patient Management System. Such initiatives hold the potential to drive increased availability of prosthetic user data to motivate government resource mobilisation for prosthetic services.

In order to accelerate data collection and the development of registries, global investments can be made to develop foundational research and parameters for data collection. For example, defining the core dataset of amputee data and outcome measures will underpin the efforts of countries to implement registries. Creation of a global platform and governance for aggregation of country-level data will enable consolidated insights. ISPO's Industry Advisory Group has launched an initiative to outline the core datasets and develop a framework for a global registry, but lacks resources to accelerate development and implementation and could benefit from additional support. Following the development of a global framework for data collection, investments in implementation and data collection efforts are needed to underpin national and sub-national planning for service expansion. See Case Study 5 for an example of the establishment of a user registry to collect such data.

CASE STUDY 4: AMPUTEE SCREENING THROUGH CELLPHONE NETWORKING (ASCENT) IN THE PHILIPPINES

The ASCENT project was developed in 2010 to address the challenge of reaching under-served communities on the islands of the Philippines. Health workers use mobile phones to record the medical history and transmit data to a centralised web-based database with photographs and videos.

Utilising ASCENT has initiated the creation of a registry of amputees from remote communities and vulnerable populations that were previously not visible to policy-makers. This data, along with other advocacy efforts, led to the creation and implementation of the Philippine Health Insurance Z Mobility, Orthosis, Rehabilitation and Prosthesis Help (MORPH) benefits package, which was launched in 2013. The package allows users to access 15,000 pesos (about USD 300) for each lower-limb prosthesis. This coverage was expanded in 2016 to 75,000 pesos (about USD 1,500) for TF prostheses.

ASCENT has not been scaled nationally or beyond the Philippines, but such tools represent potential models for countries to consider when initiating user registries and data collection efforts.

CASE STUDY 5: NATIONAL QUALITY REGISTRY FOR AMPUTATION AND PROSTHESES (SWEDEAMP) IN SWEDEN[38]

SwedeAmp was developed in Sweden in 2010 in response to the lack of data on amputees and patient outcomes from different treatment regimes in different regions and clinics. Utilising existing government health registry platforms, SwedeAmp collects patient-level data, including pre-amputation situation, amputation (level, technique used), prosthetic-fitting (device, personnel) and post-fitting (activity level achieved, and whether the patient is able to return home and resume activities). Patient outcomes are tracked until death.

SwedeAmp can show trends and predict expected outcomes of a patient, given their age, diagnosis, and location. Clinicians in the public and private sectors are mandated to manually input patient data, but progress is underway to link certain data points from other registries and electronic records. Healthcare professionals can access this dataset. Annual aggregated reports are made available to suppliers and private sector partners.

Implementing the registry has improved quality of care by allowing policymakers to identify issues in patient care and develop interventions to improve quality, based on comparing amputee outcomes across cities or facilities.[39] As a result, local guidelines for amputee and prosthetic user care have been published and strictly implemented to ensure consistency of high-quality practice.

4.6 The starting point for prosthetic services is a link between amputation and rehabilitation, but poor referral pathways lead to patient drop-off.

The care pathway for prosthetic users starts with the surgical amputation of the limb. Amputees consult with a rehabilitation specialist to be referred to prosthetic services. Amputees are then discharged for healing and recovery, before arranging to visit a service provisioning unit. The prosthetics service delivery process is then carried out. This consists of the user being assessed and measured by a prosthetist, who then prescribes and fabricates a prosthesis. The user will thereafter be fitted, and undergo gait training to learn to use and care for the prosthesis. Following the initial fitting, users often need to return to the service unit for repairs, maintenance, and to make adjustments as their residual limb or lifestyle changes.

Many amputees never enter rehabilitation, with poor linkage, low awareness of services, and lack of post-discharge follow-up as common gaps to successful referral. Lack of awareness of availability of prosthetic services from surgeons and other health workers can impact the amputation procedure, sometimes leading to requirements for revision surgery. After amputation, WHO recommends that patients should be assessed for eligibility by a medical or rehabilitation clinician and referred to prosthetic services,[40] but this often does not happen in LMICs due to low awareness of services by health workers or lack of rehabilitation staff. Patients are typically discharged from the hospital to heal after surgery, which can last up to six months. There is often no post-discharge follow-up with amputees to ensure the patient has sought rehabilitative care. Better integration and improved awareness of prosthetic services and benefits of prosthetic use in healthcare workers at primary, secondary, and tertiary levels of the health system can improve referral.

In the absence of referral pathways, user associations help to fill the gap and empower amputees to access prosthetic services. Through a network of peers, these groups provide counselling and information, even if formal referrals are not obtained through the health system. For example, the International Confederation of Amputee Associations (IC2A) is a non-profit organisation dedicated to improving the quality of life for amputees through strengthening and sharing best practices between its 15 national amputee associations. Objectives include developing peer support and mentorship models, and disseminating these models across country-based user groups. IC2A national amputee associations advocate for users to be included in government policy- and priority-setting. The IC2A champions policy changes such as setting best practices in rehabilitation and prosthetic services, and the inclusion of P&O services and products in government budgets and health insurance schemes.

[38] Kamrad I, Söderberg B, Örneholm H, Hagberg K. SwedeAmp – the Swedish Amputation and Prosthetics Registry: 8-year data on 5762 patients with lower limb amputation show sex differences in amputation level and in patient-reported outcome. Acta Orthopaedica. 2020;:1-7. Available from: DOI:10.1080/17453674.2020.1756101.
[39] CHAI expert consultation.
[40] World Health Organization. WHO standards for prosthetics and orthotics. 2017. Available from: https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/.

4.7 When patients are referred, the service point can be costly and difficult for amputees to reach.

As discussed in Section 4.2, amputees often face significant financial and logistical barriers to access services, including high indirect costs. Prosthetic service units are commonly situated in urban areas. For example, among Indonesia's archipelago of 17,000 islands, there are only 24 prosthetic service units; in Kenya, some prosthetic users in rural counties need to travel over 500 kilometres to access services. Amputees are already at a greater risk of poverty,[41] and the cost of travel for the individual and family members or personal assistants can be prohibitive. Additionally, wait times for fitting and fabrication, delays in supply of components, and physical rehabilitation add to overnight accommodation costs.

Beyond the initial fitting, the clinical pathway continues with rehabilitation and patient management occurring through multiple touchpoints during the first 1-2 years. Physical therapy is needed for numerous weeks post-fitting to ensure the user mobility using the device. Changes in activity from adopting a prosthesis will typically cause the residual limb to change in volume, which then requires prosthetists to adjust the device to ensure continued comfort and fit. Repairs and maintenance in response to wear and tear throughout the useful life of the device also require technical skills of the prosthetist. To ensure the successful fitting, adoption and continued use of the prosthesis, users need to be able to regularly access prosthetists and service units, which can incur significant indirect costs.

At present, most government reimbursement or insurance schemes do not account for these indirect costs. Some NGOs assist users with costs of travel through free overnight accommodations or reimbursement of travel expenses. One such example is 500 Miles in Malawi, where users are either provided with funds for transport or transported directly to the central provisioning facility in Lilongwe, the capital city. However, these schemes are few and far between. In their absence, users are largely left to raise funding from donations or loans from friends and family.

4.8 Decentralisation can overcome these barriers, but presently focuses on pre- and post-fitting activities in service provision and further investigation on cost-effectiveness is needed.

WHO's *Standards for Prosthetics and Orthotics* recommend a tiered approach to delivering prosthetic services that is integrated with various levels of the health system. Specialised services are available at the tertiary level, with standard services available at the secondary level. Decentralised services should be available in the primary and community levels of the health system to ensure the widest range of services can be provided as close as possible to users. Integration of prosthetic services to the lowest levels ensures appropriate patient identification, referral, and follow-up can be conducted.

A number of promising models of decentralisation have been observed in LMICs, which include satellite service centres, and patient outreach and referral through linkages with other community health programme initiatives (see Table 6). Mobile clinics have also been deployed, but face challenges with quality control of services and product delivery. Numerous challenges currently exist to scale these models.

Specialised human resources are needed throughout the process, which are limited in capacity and are thus mostly found in central facilities to serve the highest volume of patients. The cost-effectiveness of offering decentralised services needs to be further investigated: it typically requires significant additional investment by the provider, while generating considerable savings for users. Additionally, the current models for decentralisation focus on: 1) pre-fitting activities – providing referral, conducting the initial measurement and patient assessment; and 2) post-fitting activities – providing follow-ups, maintenance of devices, reassessment, and physical rehabilitation. These models do not yet permit the full decentralisation of the end-to-end fitting and fabrication process. However, integration of digital and other innovative technologies can potentially transform the process to enable full decentralisation in the future.

[41] Banks L, Kuper H, Polack S. Correction: Poverty and disability in low- and middle-income countries: A systematic review. PLOS ONE. 2018;13(9):e0204881. Available from: https://doi.org/10.1371/journal.pone.0204881.

TABLE 6: DECENTRALISATION MODELS FOR INTEGRATION OF P&O SERVICES IN LOWER LEVELS OF HEALTH SYSTEMS

MODEL	DESCRIPTION	SERVICES PROVIDED
Community-based rehabilitation (CBR) and outreach	• Typically based in or travel to various communities to identify, refer, and rehabilitate users. • May be linked with other community health initiatives. • Staffed by a range of clinicians, including CBR workers, physical therapists, and prosthetists/orthotists.	✓ Awareness-building ✓ Identification of users ✓ Assess and measure ✓ Refer to services ✓ Conduct follow up, physical therapy, and basic repairs
Mobile clinics	• A vehicle or boat can provide a limited range of prosthetic products and services. • Staffed with prosthetists/orthotists, physical therapists, social workers, and CBR workers. • Cost-effectiveness, patient adherence and quality control may be a challenge in certain settings.	✓ Awareness-building ✓ Identification of users ✓ Assess and measure ✓ Deliver final products with support of a main centre ✓ Conduct follow-up and repair
Satellite services	• Small facility that is integrated into a lower-tier decentralised health centre. • Visited by clinicians and therapists from a central full-service prosthetic service. unit. • Several satellite service sites may connect to a full-service provisioning centre.	✓ Assess and measure ✓ Deliver products with support of a main centre for fabrication ✓ Conduct follow-up and repair
Tele-rehabilitation	• Utilise digital tools, such as mobile phones and video conferencing, to: 1) connect a clinician to an amputee for direct consultation; or 2) educate and support auxiliary health workers at the community level.	✓ Identification of users ✓ Assess and measure ✓ Refer to services ✓ Conduct follow up, physical therapy and repair

CASE STUDY 6: ASSOCIATION OF PHYSICALLY DISABLED KENYA (APDK) COMMUNITY-BASED REHABILITATION AND MOBILE P&O CLINIC PROGRAMME

APDK is the oldest non-profit organisation for persons with disabilities in Kenya. It operates a network of 10 branches, each with comprehensive orthopaedic rehabilitation service, including prosthetic and orthotic services, wheelchairs, and physical rehabilitation.

To reach vulnerable populations, APDK employs a mix of CBR programmes and mobile clinics that identify and refer people with disabilities.

- CBR programmes were initiated in urban slums where people with disabilities were typically hidden in homes due to social stigma. Workers educate the community and parents on the needs of people with disabilities and the benefits of seeking services. CBR workers will also train parents and caregivers on basic therapy techniques, and advocate for the referral of patients.
- Mobile clinics bring trained clinicians to rural communities, along with assessment and fitting tools. Through the mobile clinics, patients can: 1) be assessed and referred to APDK's main site; 2) referred to a partner institution for surgical intervention; and 3) have a cast made and measurements taken of the residual limb. The mobile clinic will return with the completed device. The mobile clinic returns to each community 3-4 times per year, allowing fitted users access to maintenance or repair.

APDK is currently assessing the potential to integrate direct-casted sockets to the offerings available through the mobile clinic. If proven successful and cost-effective, this model would permit users to be fitted on the same day and closer to their home.

4.9 Innovative socket fabrication techniques can expand prosthetic services, but adoption is limited by product maturity, lack of clinical and economic evidence, and implementation guidance.

While some pre-fitting and post-fitting activities have been successfully decentralised, the socket fabrication step has remained largely tethered to a full-service prosthetic service unit. Traditional socket fabrication follows a multi-step process (see Annex G), which is difficult to de-link from personnel and infrastructure requirements. The prosthetist/orthotist's expertise is required to shape the socket so that weight is distributed in pressure-tolerant areas, which is specific to the patient's residual limb. Socket fitting is critical to the final comfort, mobility, and safety of the patient, and impacts adoption and adherence.

Socket fabrication in LMIC is affordable, but time-consuming and creates waste. Sockets in LMICs are fabricated from polypropylene or resin, through lamination of fibres. Both materials are affordable and durable. The socket fabrication and fitting process usually takes one to three days, depending on the need for adjustments. Negative environmental impact is caused by wasteful intermediary outputs that are disposed of, such as the cast of the residual limb and plaster positive mould. With traditional casting, information is lost in the process; meaning some changes require the process to be repeated.

Innovative technologies can potentially decentralise socket fitting and fabrication, and enable full end-to-end decentralisation of the prosthetic fitting process. Two different types of technologies exist: 1) direct casting; and 2) digital fabrication. Direct casting technology forms the socket material directly on residual limbs to create a socket, without the need of plaster casting or heavy machines. Fewer steps are required compared to traditional socket fabrication and the process takes one to two hours. All equipment and materials needed can be mobile. The current leading developers of direct casting technology are Amparo's Confidence socket and Össur's IceCast. While direct casting technologies look promising, further investigation into the cost-effectiveness and clinical acceptability in LMIC contexts is needed to drive adoption.

Digital fabrication utilises digital scanning to capture the shape of the limb, and software to make virtual rectifications combined with fabrication of the final socket (or the intermediary mould) from the digital file. This method replaces heavy machinery and equipment with digital tools, such as a scanner, mobile phone, laptop, and 3D printer, thereby making it potentially more cost-effective to offer in more clinics. Several companies are active in digital fabrication, with varying software, materials, and fabrication methods. Some companies, such as Prosfit and Nia, print sockets with 3D printers, albeit through different fulfilment models (the process of production, shipping, and delivery). Prosfit relies on centralised printers, which offers the benefit of centralised quality control, but requires additional shipping considerations. Nia deploys on-site, lower-priced 3D printers. Rodin, Vorum, and Proteor combine digital scanning with fabricating the positive mould of the socket using a centralised milling machine, which enables digital scans to be captured and sent to a central service which can fabricate the final socket without requiring the user to travel. In terms of market readiness in LMICs, Prosfit and Nia are the most advanced since they have conducted trials in LMICs, though further evidence generation is needed to demonstrate acceptability. Rodin, Vorum, and Proteor are commercially available in HICs, where they have focused their deployment, and currently have limited presence in LMICs.

Some 3D-printed sockets have experienced failures in laboratory testing, which differs from the slower breakage or tearing observed in sockets fabricated through other methods. These failures, which may be linked to the printing technology, could potentially cause injury or harm to users. Further research and investigation into the root causes and mitigation strategies is needed.[42] See Annex H for profiles of the main developers of novel fitting technologies currently making progress in LMICs.

While most of these technologies are commercially available in HICs, they have yet to be widely adopted in LMICs, driven by a lack of consensus on acceptability and financial implications due to insufficient clinical, operational, and economic evidence. There is potential for digital fabrication to deliver and decentralise prosthetic services more cost-effectively. Some technologies have undergone field testing in LMICs, but

[42] Pousett, B, Lizcano, A, Raschke, S. An investigation of the structural strength of transtibial sockets fabricated using conventional methods and rapid prototyping techniques. Canadian Prosthetics & Orthotics Journal. 2019;2(1). Available from: https://doi.org/10.33137/cpoj.v2i1.31008.

a lack of research standards to govern the set up and control of these trials often lead to inconclusive results that are not generalisable to other settings. For buyers and implementers to have clarity on the use of these technologies, establishing research standards, analysing cost-effectiveness, and implementation guidance is needed to drive transparency and adoption.

Prosthetic liners are an important component to the use and comfort of prosthetic devices, and are critical to the adoption of some novel socket technologies; but modern liners are cost-prohibitive in LMICs. Liners act as the interface between the skin and the socket, and are used to secure the prosthetic device, reduce slippage, ensure fit, adjust to volume change, and regulate temperature.

Over 70 types of liners are commercially available and fabricated from a number of materials. Silicone liners are most common in HICs as the material balances comfort and durability. However, since liners need to be replaced annually and are priced at USD 200 to USD 500, they are cost-prohibitive to most users in LMICs. Socket socks, bandages, or foam are commonly used instead, but such alternatives have short useful lives and often cause discomfort, which may lead to user abandonment of the entire device. Modern liners decrease dependence on walking aids, improve suspension, improve weight distribution, decrease pain, and increase comfort.[43] Field evaluation to validate whether emerging affordable liners are suitable in LMICs would enable wider adoption. Numerous innovative socket fabrication technologies require modern liners in order to be attached to the residual limb safely and comfortably. Uptake of silicone liners would enable wider adoption of these innovations.

4.10 Cost is a barrier to affordability for users and is mainly driven by the cost of prosthetic components. Prosthetists lack the market intelligence and transparency on quality of lower-cost components, which limits the penetration of these components in LMICs.

With prices ranging from USD 700 to USD 3,000,[44] prosthetic solutions from leading suppliers are not affordable to many that need them, particularly the lowest-income users. Components for a basic mechanical prosthesis – including the socket, knee joint, pylon, foot, and connectors – account for as much as 50-75% of the total cost. Contributing to the high cost of devices are the high custom duties and taxes to import components into many countries. Reducing the price of components is an opportunity to reduce overall service cost. In LMICs, there are typically limited options of components available for purchase locally. Instead, prosthetists or health administrators either hold stock of components – but have difficulties in predicting the needs of users who seek care – or place individual orders directly from overseas suppliers after patient assessment, leading to long lead times, inefficient and costly procurements, and logistical challenges.

There are a number of suppliers emerging in Asia offering affordable component options but prosthetists in LMICs have little awareness that these options are available, leading to low market penetration. LMIC practitioners are generally only aware of a few suppliers: Ottobock has earned a reputation for offering high-quality and expensive components; the ICRC and Jaipur have developed low-cost technology with decades of presence in market. Prosthetists have little knowledge of other suppliers and if they do, they often do not know how these compare in terms of quality or performance. Although international standards exist and Stringent Regulatory Authorities (SRA) regulate prosthetic components, SRA approval processes generally allow for self-declaration of conformance instead of evaluation of a regulatory dossier. This can lead to variability in quality and performance (see Figure 6 for further details). When existing standards are insufficient to guide product evaluation, brand reputation, supplier marketing efforts and user's ability to pay drive the selection criteria. Market transparency is needed on the various supply options and their comparative quality and performance in LMIC contexts. This can also help lower the barriers to entry for more competitors in LMIC markets.

[43] Stevens P, DePalma R, Wurdeman S. Transtibial socket design, interface, and suspension. Journal of Prosthetics and Orthotics. 2019;31(3):172-178. Available from: doi:10.1097/JPO.0000000000000219.
[44] Quotations and published pricing from suppliers for mechanical TF components.

FIGURE 6: QUALITY AND REGULATORY GUIDANCE FOR PROSTHETIC COMPONENTS

Prosthetic limb components are categorised as medical devices by SRAs such as the FDA and the European Commission (CE marking). In addition to SRA approval, some LMICs have regulatory processes for registration of medical devices which may or may not include prosthetics. Prosthetic components fall under the category of medical devices, which permits suppliers to declare self-conformity under US FDA (Class II, 510(K) exempt) and CE (Class I).

There are numerous quality standards for prosthetics available from the International Organization for Standardization (ISO), including: ***ISO 10328:2016*** *Prosthetics – Structural testing of lower limb prostheses – requirements and test methods* and ***ISO 22523:2006*** *External limb prostheses and external orthoses — Requirements and test methods.* These standards focus on the durability of the components and delineate requirements for structural testing of a prosthetic component in a laboratory setting. To indicate that products conform to these standards, suppliers can either invest in their own testing equipment or submit their components to a third party with specialised equipment to test prosthetic limbs, which can cost up to USD 50,000 for each set of components. Due to the high cost, some suppliers may opt to test only a few components instead of its entire product line.

ISO standards do not stipulate how components should function in LMIC settings, which can be marked by harsher environmental conditions and user lifestyles (i.e. agricultural or physical labour use cases). WHO recommends that clinical user field tests are carried out to determine the strength, durability, functionality, safety, and effectiveness of components. However, this is not a requirement under FDA or CE as prosthetic components fall under the category of medical devices, which exempts suppliers from clinical trials.

These gaps – 1) limited SRA oversight; 2) lack of LMIC considerations in standards; and 3) the high cost of testing to standards – lead to a lack of visibility on the quality of components in the market for LMIC providers. Without further quality guidance, prosthetists rely on anecdotal experience to evaluate quality.

4.11 Responsive supply channels are needed in LMICs and could be met via regional distributors.

Because patient assessment is required before components can be selected, an assortment of solutions needs to be locally available. Unfortunately, this is rarely found in LMICs since service providers often lack access to the working capital needed to maintain a large volume of components. Additionally, it is difficult to anticipate the needs of patients when making aggregate volume orders. See Annex I for limitations of common supply channels observed in LMICs. Flexible ordering from local sources and supply channels which can responsively supply tailored components to the individual users are needed.

Regional distributors aggregate volumes across buyers to purchase in bulk from international suppliers and maintain a wider range of inventory that can effectively meet various user needs. Purchasing currently occurs through disorganised, ad-hoc patterns with individual purchasers each choosing their own channels, which includes placing individual orders directly with international suppliers. This leads to high delivery costs and long lead times. Organisation and aggregation of ordering can improve quality and affordability through expanded product options, reduction of delivery lead time, and logistical costs. Distributors that focus on prosthetic components operate successfully in some LMIC markets (see Case Study 7) and help drive efficiency and affordability by aggregating orders, negotiating volume-based pricing, offering extended payment terms to buyers, and delivering responsively to providers. With additional support, they can improve upon their capacity as an intermediary between buyers and suppliers and organise efficient markets. Such support can help these distributors increase access to working capital financing, enable geographic expansion, and expand warehouse capacity.

CASE STUDY 7: ORGANISATION AFRICAINE POUR LE DÉVELOPPEMENT DES CENTRES POUR PERSONNES HANDICAPÉES (OADCPH)

OADCPH is a Togo-based non-profit regional distributor that links international manufacturers with providers in Africa. OADCPH serves a network of 80 members in more than 30 African countries, which includes public and private rehabilitation centres, individual prosthetists/orthotists, NGOs, FBOs, and governments.

The annual membership fee is USD 80 and members must agree to abide by a code of ethics for setting sustainable and affordable margins. OADCPH's members benefit from negotiated pricing from bulk orders placed annually from a range of international suppliers. OADCPH has a 600m^2 warehouse for storing inventory and can deliver components in a number of countries in as quickly as 24 hours.

Because of its reputation and access to prosthetists/orthotists in Africa, OADCPH has been able to negotiate working capital financing with suppliers and in turn offers extended payment terms to buyers. OADCPH also disseminates product information from suppliers to its members to better inform product selection and purchasing decisions. OADCPH is currently piloting a 3D printing orthotics project with HI to supply orthotic components to regional members from a 3D printer centrally housed at its warehouse. OADCPH has also developed a regional training centre that offers a roster of training programmes for prosthetists/orthotists and other rehabilitation professionals, covering technical skills, service unit management, and administration and professional development.

Looking ahead, OADCPH is planning to expand warehousing capacity and its presence to East and Central Africa. It hopes to access increased working capital financing to offer better payment terms to more providers. It also hopes to strengthen its educational and training programmes, and sets ambitions on setting up a regional component testing centre to evaluate the quality and performance of components that passes through its distribution channels.

4.12 Irrespective of the delivery approach, human resource (HR) capacity is a limitation, and novel ways of expansion and extending HR need to be considered.

To support the adoption and scale-up of innovative fitting technologies, consideration needs to be made for shifts in HR requirements. The traditional fitting process relies heavily on the skill level of the prosthetist/orthotist in order to control quality, which also limits how quickly services can be expanded and whether services can be decentralised. For novel technologies, certain steps such as digital scanning could potentially be task-shifted to lower-level or non-P&O healthcare workers. Conversely, direct fitting or digital rectification requires prosthetists/orthotists to be trained in new techniques and skills. Thus, the scale-up of these technologies is highly dependent on adequate investment in training P&O and other clinicians to successfully integrate these tools into their workflow.

Investing in capacity expansion of prosthetists/orthotists and leveraging models of HR extension are critical to address the gap of prosthetists/orthotists in LMICs. Trained prosthetists/orthotists are central to ensuring high-quality, well-fitted prosthetic solutions, regardless of the provisioning approach selected. Sufficient capacity of prosthetists/orthotists is a key pillar of any functioning prosthetic services system. Investment is needed to increase the number of prosthetists/orthotists, and to upskill and retain existing practitioners by investing in training, developing career pathways, and adequate job benefits. Novel models are emerging which use digital technologies to cost-effectively expand training and extend the reach of clinicians to reach more patients, thereby lowering barriers to access. These models need further validation and support in order to reach wider adoption and achieve impact.

TABLE 7: OPPORTUNITIES TO EXPAND AND EXTEND HR CAPACITY

MODEL	DESCRIPTION	IMPACT ON ACCESS
Blended online-offline P&O training	Virtual learning modules and online lectures, combined with practical technical skills through a short period of on-site learning at a regional school or through mentorship in their current P&O workplace and role.	• Decreases the time on-site • Lower cost • No loss of income for current practitioners who are upskilling by continuing employment
Video- or phone-based rehabilitation and gait training	Mobile applications use motion sensors on the user to provide coaching prompts to facilitate gait training without a physical therapist. Video conferencing for physical therapists to provide training advice and answer user questions during rehabilitation after the user has left the service centre.	• Remote services / no travel • Lower cost • Extends the reach of rehabilitation clinicians without the need for travel
Task-shifting	Utilising digital scanning technologies, and under the supervision of rehabilitation clinicians (i.e. physical therapists, prosthetists/orthotists, rehabilitation therapists), the assessment and measurement step in the fitting process could be task-shifted to primary and community-level health workers.	• Extends certain skills of prosthetists/orthotists to other health workers • Reduces need for centrally based rehabilitation clinicians to travel

5. Market Challenges

LMIC markets for prosthetic services have been limited by the lack of service capacity, with a need to rally political prioritisation and funding to invest in expansion, and to support users to access prosthetic services. The key demand and supply dynamics that have presented challenges to user access and sustainability of the market are summarised in this section.

5.1 Demand

Awareness	**Policy-makers, clinical providers, and users lack awareness on the availability, importance, and value of prosthetic services.** • **POLICY-MAKERS:** Do not recognise or understand the need, importance, and economic impact of providing prosthetic devices. This is driven by the lack of local data on amputees and affects prioritisation in policy-making, programming, and financing. • **PROVIDERS:** Healthcare workers (i.e. physicians, surgeons) do not consider the need for a prosthetic device during amputation and therefore an amputee may require revision surgery in order to accommodate for prosthetic fitting. Primary health workers who identify amputees are not aware of referral pathways for prosthetic services. • **USERS:** Amputees discharged after surgery without referral or information may not be aware of the availability of prosthetic services or how to access them. Amputees may also not be aware of the health and economic benefits that prosthetic devices offer.
Political Will	**The political will in LMICs to develop and regulate service capacity is low. NGOs have filled part of the gap, which sometimes results in parallel systems.** Services often fall under the purview of multiple Ministries, such as Health, Social Welfare, and Veteran Affairs. Political buy-in and coordination is needed across all these agencies in order to allocate sufficient funding and mobilise strategic planning. Due to the lack of data and understanding of the economic benefits, governments have not exhibited the will to invest in service capacity. The resulting gap has been partially addressed by NGOs and FBOs, which has often led to parallel systems for provisioning and procurement. Though NGOs often work in collaboration with and support government initiatives, government leadership is needed to regulate the sector.
Financing	**Funding for investments in prosthetic service capacity as well as for products and services is inadequate. Out-of-pocket (OOP) expenditure is high.** Prosthetic services are expensive and not affordable to many people that need them. Where reimbursements or insurance schemes are available, they generally do not cover the full cost of the device and service. Additionally, since there are few access points, amputees must travel long distances to reach urban centres, incurring incremental costs for travel, accommodation, and lost wages. These are rarely accounted for in reimbursement schemes.
Provision	**Provision is limited by a low number of trained prosthetists/orthotists and lack of access points. Adoption of technologies to decentralised services is slow.** Delivering prosthetics requires specialised equipment and personnel. Thus, services are tethered to physical service units, which are expensive to set up and therefore only found in central locations. Decentralisation of the service delivery process is limited to certain activities. LMICs do not have enough trained practitioners. Where trained HR capacity is available, poor professional recognition, pay, and work conditions lead to high attrition. Several socket fitting and fabrication innovations have the potential to untether those steps of the service provisioning process from service units, but have not scaled due to a lack of comprehensive implementation, and economic and clinical evidence.

5.2 Supply

Supply Landscape	**Providers do not have enough product options to meet users' varying needs and current modular options in LMICs are expensive** Prosthetists/orthotists in LMICs need access to an adequate assortment of affordable high-quality components to meet the needs of different users. LMIC supply options mainly consist of expensive components from a few leading global manufacturers and affordable conventional prosthetic solutions. The latter may be sub-optimal for all users since they lack customisability. Providers are not aware of the full range of affordable component options from manufacturers in Asia as these companies have limited presence and have not invested in LMIC market entry. As a result, users who desire modular components are limited to options they cannot afford.
Efficient Supply Channels	**Providers in LMICs are not supported with responsive local supply chains that allow for flexible ordering depending on patient prescription.** Very few regional or local distributors supply prosthetic components, so prosthetists often place individual orders directly with international manufacturers. This delays fitting and increases logistics costs and prices to end users. High custom duties and taxes for importing components further challenges affordability. Distributors who can aggregate and offer an assortment of prosthetic component options locally enable responsiveness to better serve prosthetists and users.

5.3 Enablers

Data	**There is a no defined set of outcome measures to: 1) quantify economic benefits from prosthetics; and 2) assess performance of new technologies or components.** The availability of numerous approaches to quantify various aspects and benefits of prosthetics, such as quality of life, mobility, comfort score, walk tests, etc., lead researchers to cherry-pick outcome measures, which leads to inability to generalise results and compare products. A defined set of outcome measures will be critical to the implementation of systematic data collection, serve as the baseline of research studies, and to help inform economic return on investment.
Quality	**There is a lack of market transparency to guide prosthetists and users on the quality of different prosthetic solutions.** ISO quality standards focus on durability in laboratory testing and do not take into account the performance of the components in a LMIC context or when fitted to a user. They are therefore insufficient to guide product selection. Since SRA approvals, such as CE and FDA, are obtained through self-declaration with minimal oversight, not all components from a supplier may have undergone the same durability testing. As such, providers cannot rely on SRA approvals to indicate quality and performance of different components, leaving prosthetists to rely on anecdotal feedback or ad-hoc field testing.
Research Standards	**Lack of 'gold standard' research guidance has led to poorly designed clinical and implementation studies that lead to inconclusive results and little guidance for market actors** Studies conducted in the prosthetics sector lack consistency in the robustness of design to generate clinical, economic, and implementation evidence. As a result, prosthetics research often generates inconclusive results that are difficult to generalise or apply to other scenarios or settings. Defining minimum research standards is necessary to raise the quality of studies conducted and produce industry-accepted findings.

Photo Credit: CDPF

CHAPTER 2:

STRATEGIC APPROACH TO MARKET SHAPING

6. Strategic Approach to Market Shaping and Market Building

Increasing access to prosthetic services to address the unmet need of users in LMICs will require a multi-faceted approach that leads to long-term, sustainable access. Interventions that address global barriers to market access, encourage political prioritisation to increase prosthetic service capacity, accelerate the scale-up of innovative fitting technologies, and ensure local availability of affordable high-quality components are foundational to market access. This section proposes five strategic objectives and long-term desired outcomes that will build and strengthen the market for prosthetics services.

STRATEGIC OBJECTIVE 1: Develop foundational datasets to inform the investment case for prosthetic services and guide the development of standards.

Barriers addressed	**Data** • Lack of data in LMICs hinders understanding how many amputees are (un)able to access prosthetic services. **Awareness and financing** • Without such data, policymakers do not prioritise investments in expanding the sector.
Rationale	• Mechanisms for structured data collection – such as registries – have proven to positively impact investment and service delivery. • To initiate data collection, consensus on a core dataset of amputee/user data is needed. • Outcome measures and quantifying need can underpin the analysis of economic and health benefits for investing in prosthetic services.
Proposed activities	• Build consensus on outcome measures to underpin and standardise data collection and guide research in prosthetics. • Define the core data set useful to the industry, national, and international institutions to support policymaking and funding. • Design and implement mechanisms for data collection at global and country levels. • Develop the investment case – i.e. quantify economic returns to user, family, community, economy – for donors and LMIC governments to invest in prosthetics services.
Target outputs	• Consensus on priority outcome measures and core data set. • Registry of amputees, adopted in LMICs, that is linked to a global platform. • An investment case which quantifies economic benefits of investing in prosthetic services.
Long-term outcome	• Political prioritisation and long-term investments by policymakers and donors.

STRATEGIC OBJECTIVE 2: Support countries to define appropriate policies and invest in the key requirements of a functioning prosthetic provisioning system.

Barriers addressed	**Political will and financing** • Low political will from LMIC governments leads to a lack of investment and leadership in establishing prosthetic services. • There is limited reimbursement for users, who then have high OOP expenditures. **Provision** • Prosthetic services require specialised human resources and infrastructure, both of which are costly to establish. LMICs have limited number of service units, largely in urban centres. • Users typically travel long distances, resulting in high indirect costs (i.e. travel, loss of income, accommodation, and caregiver costs).
Rationale	• Setting up a functioning prosthetic services system that is integrated with the healthcare and related service (i.e. wheelchair) systems will require significant investment in infrastructure and personnel. • Affordability is a barrier; users cannot access enough funds to cover all costs, including indirect costs. • Models of co-investments with the private sector are emerging, but require validation and support to achieve financial sustainability.
Proposed activities	• Support governments to develop a costed plan for prosthetic service expansion and coordinate funding with investments from different sources. • Support governments to simplify market entry requirements (i.e. registration, duties) for component suppliers and organise purchasing through local distributor channels. • Support LMICs to train, accredit, and hire prosthetists/orthotists to increase human resource capacity. • Pilot innovative models of user financing. • Validate and expand proven public-private partnership investment models for prosthetic services.
Target outputs	• Increased capacity of accredited prosthetists/orthotists. • Costed national plans, supported with dedicated long-term funding for prosthetic services coordinated across various government and non-government sources. Policies that describe outreach, referral, financing, and decentralised prosthetic services at various levels of the health system including primary, community, and rural communities. • Clear market entry guidance for component suppliers. • Reduced customs, taxes, and duties on imported prosthetic equipment and components.
Long-term outcomes	• Increased coverage of prosthetic device use in countries with political will. • Improved availability of quality prosthetic services. • Affordable prosthetic component suppliers enter LMIC markets.

STRATEGIC OBJECTIVE 3: Accelerate market validation and adoption of innovative technologies that can simplify, decentralise, and lower the cost of prosthetic service provision.

Barriers addressed	**Research standards** • No research standards to set minimum requirements for prosthetic research leads to poor set-up and execution of research, leading to inconclusive results. **Provision** • Fitting innovations have the potential to decentralise certain aspects of provisioning, but have been not been scaled due to a lack of implementation, and economic and clinical evidence in LMICs. • Implementers lack clarity on technologies which could be deployed to strengthen service delivery models.
Rationale	• LMIC implementers need further clarity on whether innovative fitting technologies are suitable and cost-effective for their context, which requires further evidence gathering and expert consensus. • Current studies are not generalisable to other settings.
Proposed activities	• Define research standards to set minimum requirements and guidance for researchers and suppliers who conduct prosthetics research. • Close evidence gap and drive consensus on innovative fitting technologies that are ready to be scaled. • Support high-potential innovators to improve business models and operations to enter LMIC markets and achieve scale and financial sustainability. ▪ For example, support validation in LMIC settings to increase availability of affordable silicone prosthetic liners.
Target outputs	• Minimum standards for conducting research and implementation guidance. • New evidence on novel technologies. • Policy guidance or industry consensus issued on adoption of novel technologies. • Increased penetration of prosthetic liner use due to affordability, availability, and market validation.
Long-term outcome	• Increased capacity to deliver services in LMIC settings with increased efficiency.

STRATEGIC OBJECTIVE 4: Accelerate uptake of affordable, quality prosthetic components by increasing market transparency to empower buyers to make value-based purchasing decisions.

Barriers addressed	**Supply landscape** • LMIC markets have limited component options, due to lack of provider awareness of more affordable options and lack of incentives for those suppliers to invest in market entry. **Quality** • Existing quality standards do not consider requirements for LMIC contexts, thus lack of transparency on the durability and acceptability limits uptake.
Rationale	• LMIC supply is largely limited to high-priced HIC suppliers or low-cost NGO options, which may not be suitable or affordable to all users. • Lower-cost components are available in global market but have little market penetration in most LMICs, because of lack of information on these product options for buyers and low market transparency on their quality and performance in LMIC context.
Proposed activities	• Increase market transparency of the global supplier landscape to buyers. • Drive transparency of quality of affordable components by developing a standard for evaluating suitability of components in LMIC settings. • Incentivise market entry of affordable high-quality component suppliers in LMICs through developing market tools and roadmaps, and providing catalytic procurement.
Target outputs	• Improved guidance and clarity on product selection for clinicians, procurers, and users.
Long-term outcomes	• Increased availability of affordable high-quality prosthetic components in LMICs. • Empowered buyers can make comparisons across component suppliers to select products best suited to the needs of user and context.

STRATEGIC OBJECTIVE 5: Strengthen regional supply to increase affordability and availability of quality prosthetic components.

Barriers addressed	**Efficient supply channels** • Prosthetics components are selected based on amputee assessment; thus local, responsive supply channels are needed to support providers. • Lack of flexible supply forces prosthetists and other buyers to procure ad-hoc from overseas suppliers, which can lead to delays in fitting and high costs to user.
Rationale	• Regional distributors have emerged that maintain component inventory and aggregate volumes across numerous buyers to achieve better pricing and responsive supply.
Proposed activity	• Strengthen regional distributors to access financing to expand capacity, improve service and product offerings, and reach more buyers.
Target outputs	• Responsive supply channels that leverage effective regional or local distribution models. • Increased affordability of prosthetic services due to reduction in wait times, more efficient supply processes, and lower landed cost of components.
Long-term outcome	• A competitive, healthy local market of an assortment of affordable prosthetic component options ready to meet the needs of all users.

7. Next Steps

This document was developed to support the identification of activities that will support increased and sustainable access to appropriate and affordable AT. As an overall investment and implementation strategy is developed, some of these proposed activities will be undertaken in the immediate term by the AT2030 programme, which is funded by UK aid and led by the Global Disability Innovation Hub, to test what works to increase access to affordable AT. Others will be complementary early investments that ATscale will take on or will become foundational to ATscale's long-term investment in the space.

As interventions are shown to be effective, the investment case outlining the magnitude and types of investment needed will be further refined and developed. It is expected that different large-scale investments and financial instruments will be needed to achieve long-term outcomes. For example, system-strengthening grants may be needed to support the integration into the health system, while match funding or co-investments may catalyse government procurement and investment. On the supply side, donor investment may be leveraged to de-risk private investment in cost-effective supply mechanisms.

ANNEXES

ANNEX A: LIST OF CONSULTATIONS FOR PRODUCT NARRATIVE DEVELOPMENT

ORGANISATION	NAME
500 Miles	Austin Mazinga
Amparo	Lucas Paes de Melo
Association of Physically Disabled of Kenya (APDK)	Benson Kiptum
	Joseph Gakunga
	Gladys Koech
Beijing JingBo P&O	Qing Hong An
Beijing P&O Technique Centre	Linda Zhu
Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS)	D.R. Mehta
	V.R. Mehta
Blatchford/Endolite	John Ross
Cambodian School of Prosthetics and Orthotics (CSPO)	Sisary Kheng
Click Medical	Jimmy Capra
Clinton Health Access Initiative (CHAI)	Jean Bosco Uwikirebera
CURE Hospital	Seith Simiyu
	Nelson Muoki
	Michael Mbote
Exceed	Carson Harte
Fujian Guozi Prosthetics	Jianwei Pan
Humanity and Inclusion (HI) (formerly Handicap International)	Isabelle Urseau
	Abderrahmane Banoune
	Jérôme Canicave

ORGANISATION	NAME
International Confederation of Amputee Associations (IC2A)	Dr. Nils-Odd Tonneyold
	Dieter Juptner
	Jean-Pascal Hons-Olivier
	Sandra Sexton
International Committee of the Red Cross (ICRC)	Marc Zlot
	Jess Markt
International Society of Prosthetics and Orthotics (ISPO)	Friedbert Kohler
	Claude Tardif
Jaipur Foot, Nairobi	Kundan Doshi
	Francis Asiema
Kenya Ministry of Health	Alex Kisyanga
LegWorks	Emily Lutyens
Metiz	Elena Morozova
	Mohamed Bassiouny
MiracleFeet	Chesca Colloredo-Mansfeld
Nia Technologies	Jerry Evans
	Matt Rato
Organisation Africaine pour le Développement des Centres pour Personnes Handicapées (OADCPH)	Masse Niang (also of FATO)
	Anarème Kpandressi
Ottobock	Berit Hamer
Prosfit	Alan Hutchison
	Christopher Hutchison
Prosthetist/orthotist, Fiji	Dean Clarke
Proteor	Frederic Desprez
Puspadi Bali	Ni Nengah Latra
Regal Prosthesis	Oriana Ng
Rehab Impulse/Alfaset	Roger Ayer
South Africa P&O / physical therapist	Liezen Ennion
	Johann Snyder

ORGANISATION	NAME
ST&G Corporation	Glenn Choi
SwedeAmp/CEPO	Bengt Soderberg
Tanzania Training Centre for Orthopaedic Technologists (TATCOT)	Longini Mtalo
Teh Lin Prosthetics	Brian Chen
	James Chen
University Don Bosco, El Salvador	Monica Castaneda
University of Global Health Equity	Claudine Humure
University of Melbourne	Wesley Pryor
United States Agency for International Development (USAID)	Michael Allen
	Kirsten Lentz
Vorum	Nam Vo
World Health Organization (WHO)	Chapal Khanabis

ANNEX B: DESIGNATIONS IN PROSTHETIST/ORTHOTIST PROFESSIONS ACCORDING TO 2018 EDUCATION STANDARDS (DETAILED)

DESIGNATION	RESPONSIBILITIES	REQUISITE TRAINING	RECOMMENDED #
CLINICIANS			
Prosthetist/Orthotist *Formerly: Category I Prosthetist/ Orthotist*	• **Clinical Services:** clinical assessment, prescription, technical design, fabrication, and fitting of devices; monitoring outcomes. • **Leadership:** management of service units; advance models and/or methods of service delivery by integrating best available evidence, or new technologies; supervising and training clinical and non-clinical personnel; participation in community-based rehabilitation; advocacy for P&O services and professionals in professional organisations and government agencies. • Training, education, community demonstrations, awareness-building.	• 4 years of full-time study at university level. Curriculum includes: practical techniques for fitting/ fabrication techniques across a wide range of prosthetic-orthotic device types. • Theoretical topics: clinical conditions, anatomy, physiology, pathologies, biomechanics, materials technology. • Clinic management: leading clinical teams, inventory management, budget management, training and supervision, occupational hazards, ethical code, research methods.	• 5-10 prosthetist/ orthotist clinicians per million; though in HICs, it is usually 15-20 per million. • Each service point should have at least one qualified clinician, ideally Category I Prosthetist/Orthotist or an experienced Associate Prosthetist/ Orthotist). • Each clinician can be expected to provide complete services to 300-600 users per year.
Associate Prosthetist/ Orthotist *Formerly: Category II Orthopedic Technologist* *and* *Category II "Specialised" (according to their area of training (i.e. prosthetics, lower-limb orthotics, etc.) Technologists*	• **Clinical Services:** clinical assessment, prescription; technical design, fabrication, and fitting of devices; monitoring outcomes. • Associate Prosthetists/ Orthotists are capable of carrying out all tasks allocated to orthopedic technologists, but only in one speciality branch.	• 3 years of formal structured education which covers many of the topic areas of the Prosthetist/Orthotist curriculum but to a lesser depth, and with a greater focus on clinical services and fabrication. • Associate training in one single discipline usually takes 12-18 months. Thereafter, they are named according to their area of expertise (i.e. Associate Prosthetist, Associate Lower Limb Orthotist)	

DESIGNATION	RESPONSIBILITIES	REQUISITE TRAINING	RECOMMENDED #
NON-CLINICIANS			
Prosthetist/Orthotist Technician *Formerly: Category III Prosthetic/Orthotic Technician/Bench Worker*	• **Non-clinical services:** Support (Associate) Prosthetists/ Orthotists in device fabrication, assembly, maintenance, and repair. Expertise in material science, technical procedures, and safe practices, but does not have clinical contact with users (i.e. making fitting adjustments or alignments). • Not involved in direct services to the user. However, in LMICs, lack of capacity often means Prosthetist/ Orthotist Technicians are also directly working with patients, typically under the guidance of a Prosthetist/Orthotist / Associate Prosthetist/ Orthotist.	• 2 years of formal structured or 4 years of on the job/in-house training. • Curriculum includes practical technical training and basic understanding of material science and safety procedures.	• Each clinician should be supported by 2 non-clinicians; thus 10-20 non-clinicians are needed per million. • In decentralised units with a shortage of clinicians, increasing the ratio of non-clinicians can effectively extend the service team.

ANNEX C: GLOBAL COMPONENT SUPPLY LANDSCAPE

SUPPLIER	COUNTRY	MECHANICAL TF PROSTHETIC*	WEBSITE	QUALITY CERTIFICATION	LMIC AVAILABILITY
Beijing Jingbo	China	USD 250-500	www.en.jingbo-po.com	ISO, CE	Asia, Southern Africa
Blatchford/ Endolite	UK/ India	over USD 1,000	www.endoliteindia.com	ISO, CE	South and Southeast Asia
Fujian Guozi Rehabilitation	China	under USD 250	www.fpcfoot.com	ISO, CE, FDA	East Asia
Metiz	Russia	USD 500-1,000	www.metiz-ltd.com	ISO, CE	Asia
Nobel Prosthetics	Hong Kong/ China	USD 500-1,000	www.nobel.hk	ISO, CE	Latin America, Asia, Middle East, Africa
Ortotek	Turkey		www.ortotek.com	ISO, CE	Asia, Latin America, Middle East, Africa
Össur	Iceland	over USD 1,000	www.ossur.com	ISO, CE, FDA	Southeast Asia, Southern Africa
Ottobock	Germany	over USD 1,000	www.ottobock.com	ISO, CE, FDA	Asia, Africa, Latin America
Proactive Technical Orthopedic	India	under USD 250	www.protechortho.com	ISO, CE	50+ countries
Proted	Turkey	USD 500-1,000	www.protedglobal.com	ISO, CE	46 countries
Proteor	France	over USD 1,000	www.proteor.com	ISO, CE, FDA	French-speaking Africa
Teh Lin	Taiwan	USD 500-1,000	www.tehlin.com	ISO, CE, FDA	Asia, South and North Africa

* knee, pylon, ankle, foot, connectors.

ANNEX D: SELECT PROSTHETIC COMPONENTS DEVELOPED FOR LMIC CONTEXT

TECHNOLOGY	SUPPLIER	PRICE	DESCRIPTION	AVAILABILITY
Agilis Prosthetic Foot	ICRC Switzerland www.blogs.icrc.org/inspired/2019/05/05/affordable-feet-icrc-agilis-prostheses	under USD 100	Designing a low-cost carbon foot with increased comfort and mobility.	Under development
Alice Limb	Blatchford/Endolite UK/India www.endoliteindia.com	USD 500-1,000	Low-cost modular prosthetic components.	Predominantly India
All-Terrain Knee	LegWorks USA www.legworks.com	USD 200 (in LMICs)	Mechanical knee that gives a natural swing without hydraulic or pneumatic technology. Waterproof, can be used in dusty, hot environments. Can be fitted for active and low-mobility amputees.	~30 countries
Emergency Limb	Proteor France www.proteor.com	USD 500-1,000	Temporary prosthetic limb with partially-fitted socket, that can be strapped and adjusted to amputees to provide temporary mobility in emergency settings.	Available through HI
'ICRC' Polypropylene System	ICRC Switzerland www.icrc.org/en/doc/assets/files/other/icrc-002-0913.pdf	USD 200-800	Launched in 1993, ICRC has developed prosthetic devices composed of polypropylene components that are produced in high volumes in Switzerland.	Available throughout LMICs
ReMotion Knee	D-Rev US www.d-rev.org	USD 80 (in LMICs)	Mechanical, polycentric knee, water-resistant and durable; developed through Jaipur.	~30 countries

ANNEX E: OVERVIEW OF PROMINENT INTERNATIONAL ORGANISATIONS PROVIDING PROSTHETIC SERVICES[45]

	INTERNATIONAL COMMITTEE OF THE RED CROSS (ICRC)	BHAGWAN MAHAVEER VIKLANG SAHAYATA SAMITI (BMVSS)	HUMANITY & INCLUSION (HI)
	www.icrc.org	**www.jaipurfoot.org**	**www.hi.org**
About	Independent international organisation that focuses on humanitarian protection and assistance for victims of armed conflict and situations of violence.	Registered Indian NGO with the aim to provide mobility and dignity to people with disabilities.	International independent aid organisation focused on working with people with disabilities affected by poverty and exclusion and conflict and disaster.
Established	ICRC launched the Physical Rehabilitation Programme in 1979.	Founded in 1975, in response to polio crisis in India.	Founded in 1982, in response to landmine victims in Cambodia and Thailand.
Geographical coverage	170+ rehabilitation centres in 40+ countries in the Middle East, Africa, and Southeast Asia.	23 sites in India, with presence or partnerships in 27 countries. BMVSS has also held 73 temporary fitting camps in 30 countries.	94 rehabilitation projects in 49 countries, including Africa, the Middle East, Asia, and Central and South America.
Approach	The Physical Rehabilitation Programme was set up to support the physical rehabilitation of amputees by providing technical support and training to establish services, and to fit and supply mobility devices, prosthetic devices, or wheelchairs. Support also includes long-term rehabilitation, education, and social and economic inclusion.	BMVSS offers free prosthetic devices through a broad network of service points across India and through partners in other countries. All users are fitted within one day. Supported by private and public donors, including the Ministry of External Affairs of the Government of India.	HI initiates projects in emergency response at the invitation of governments, with the goal to transition from emergency response to developing comprehensive services over time.
Impact	In 2017, supported 144 rehabilitation centres in 36 countries, providing 26,000 prostheses through local partnerships. ICRC focuses on conflict, humanitarian crises, and natural disasters; working through local partnerships to ensure long-term sustainability.	To date, the organisation has rehabilitated more than 1.8 million people with physical disabilities, at a rate of 60,000-80,000 users per year. Primary focus of impact is India, where BMVSS produces and delivers an estimated 25,000 prosthetic limbs per year, roughly 50% of the total market.	HI has supported access to physical rehabilitation services and products to 277,194 people. In 2018, it delivered 25,025 P&O devices.

[45] Source: CHAI expert consultations with NGOs and organisation websites as denoted in Annex A.

	INTERNATIONAL COMMITTEE OF THE RED CROSS (ICRC)	BHAGWAN MAHAVEER VIKLANG SAHAYATA SAMITI (BMVSS)	HUMANITY & INCLUSION (HI)
Technology	In 1993, ICRC developed a low-cost polypropylene prosthetics solution, which won the ISPO Blatchford Prize for innovation because of its suitability for deployment in LMICs. Until 2019, it was supplied by Swiss-based CR Equipment. In 2019, ICRC has switched to Alfaset, a non-profit arm of manufacturer Rehab Impulse, also Swiss-based. ICRC's prosthetic solution is deployed in ICRC-supported rehabilitation centres, as well as being available for purchase by other providers and service centres.	BMVSS centrally manufactures partially formed prosthetic limbs and other components in its manufacturing centre in Jaipur, India. The intermediary product, made from rubber and polypropylene, is then heated and formed into the final prosthetic device at the site of fitting. The device features a low-cost non-articulated foot and shank. It cost USD 50 to produce. BMVSS's Jaipur Foot component revolutionised foot componentry when it was released because it was low-cost, had a flexible keel and was able to be used appropriately in an Indian context (permitted squatting, cross-legged sitting, and used with sandals). The overall Jaipur lower-limb solution is shown to be unsatisfactory biomechanically, but continues to be deployed because of the low cost.	HI does not produce its own components and deploys modular components from a range of international suppliers. In partnership with Proteor, HI has developed an emergency prosthetic limb that can be fitted to any user to enable temporary mobility in conflict zones. HI has also been conducting implementation research in the digital fabrication of orthotics and prosthetic sockets, testing for acceptability, cost-effectiveness of these technologies in various LMIC settings.

ANNEX F: SELECT REGIONAL NGO/FBOS

ORGANISATION	GEOGRAPHICAL COVERAGE	MODEL	IMPACT
500 Miles (Est. 2007) **www.500miles.co.uk**	Focused on Malawi and Zambia, some presence in Tanzania (Zanzibar).	• Sponsors the training and accreditation of 18 prosthetists/ orthotists. • Offers free P&O services and devices at the Kamuzu central hospital in Lilongwe as well as through community outreach services. • Provide funds to users who have to travel for transport and accommodation. • Funding comes from government, and support from other local partners and donors.	• Has fitted over 3,500 users. • Sponsored the training and accreditation of 18 prosthetists/ orthotists at ISPO-accredited training schools.
Mobility India (Est. 1994) **www.mobility-india.org**	India (South, East and North-Eastern States).	• Provides rehabilitation services and mobility devices including P&O to the most vulnerable populations. • Provide prosthetist/orthotist training through its Rehabilitation Research and Training Centre in Bangalore. • Develops and manufactures low-cost components and mobility products that are designed for LMIC contexts. • Committed to employing persons with disabilities in its operations and in its training programmes.	• Provided over 220,000 assistive devices and interventions. • Trained over 5,000 rehabilitation personnel. • Community outreach programmes have reached 6,000 persons with disability, and reached 402 urban slums and rural communities.
CURE (Est. 1996) **www.cure.org**	9 hospitals. Programmes in 27 countries, including Kenya, Uganda, Malawi, Zambia, and Ethiopia.	• International Christian FBO. • Establishes and operates orthopaedic paediatric charitable hospitals, and offers a full range of care from surgical treatment to rehabilitation and fitting of mobility devices. • Specialised programmes focused on birth defects and neuro-orthopaedic disorders such as club foot, spina bifida and hydrocephalus. • Although medical and surgical interventions are provided free of charge, mobility devices are typically paid for OOP.	• Performed over 213K orthopaedic operations on paediatric patients.

ORGANISATION	GEOGRAPHICAL COVERAGE	MODEL	IMPACT
Association of the Physically Disabled Kenya (Est. 1958) **www.apdk.org**	Kenya.	• Charitable organisation that offers range of services to identify, rehabilitate, and reintegrate people with disabilities. • Services include medical rehabilitation, provisioning of mobility devices including P&O, physical therapy, community-based rehabilitation, education, vocational and skills training, and micro-financing for entrepreneurs with disabilities.	• Rehabilitated over 600,000 persons with disabilities. • In 2018, 1,698 clients were attended to, 53 orthopaedic operations sponsored and 497 orthopaedic devices provided.
Puspadi Bali (Est. 1999) **www.puspadibali.org**	Eastern provinces of Indonesia.	• Non-profit organisation that focuses on providing mobility devices and rehabilitation services to persons with disability. • Services include outreach to remote islands to identify and refer amputees and build awareness, production of lower limb P&O devices, provision of wheelchairs, and advocacy for policy reform at local and national levels. • P&O devices are provided free of charge.	• Provides services to 580 people every year, 400 of which are for P&O devices: 160 TF, 100 TT, and repairs for ~200 users. • Around 65% of the 20 staff are physically-disabled.
Limbs International (LI) (Est. 2004) **www. limbsinternational.org**	15 countries, including Kenya, India, Indonesia, and Mexico.	• Developed a 'Limbox' solution that contains all components required to fit a TF amputee (not the socket). This low-cost solution (USD 600) won the Drucker prize for innovation in 2019. • Utilises partners to identify potential users who have access to a community-based rehabilitation programme and provides the Limbox free of charge.	• In 2018, LI delivered 400 limbs.
Range of Motion Project (Est. 2005) **www.rompglobal.org**	Guatemala, Ecuador, and US.	• Non-profit organisation that provides support to develop local capacity (training prosthetists and local manufacturing), providing medical care to those with physical disability, and developing and deploying innovative prosthetic technologies. • Engages in advocacy and awareness-building activities.	• 9,249 patient visits, with 3,345 devices delivered since establishment.
Exceed Worldwide (Est. 1989) **www.exceed-worldwide.org**	South & Southeast Asia (Cambodia, Sri Lanka, Indonesia, Philippines, Myanmar)	• Supported the establishment of P&O training schools. • Develops capacity of ISPO-accredited professionals for expansion of services in region. • Expanded P&O services through social enterprise model with pricing based on ability to pay.	• Established 5 P&O schools in region and trained over 500 professionals. • Supplied over 55,000 custom-made P&O devices.

ANNEX G: DESCRIPTION OF TRADITIONAL SOCKET FABRICATION AND FITTING PROCESS

TRADITIONAL SOCKET FABRICATION PROCESS		
1. Negative mould	Made by wrapping residual limb with a wet plaster-of-Paris bandage.	
2. Positive mould	Made by filling the cast with a mixture of plaster-of-Paris and water	
3. Rectify	Rectifications are made to the positive mold.	
4. Socket formed	Socket is formed by draping polypropylene or using laminated resins.	
5. Final changes	Final adjustments to the socket made using machinery, suspension attached.	

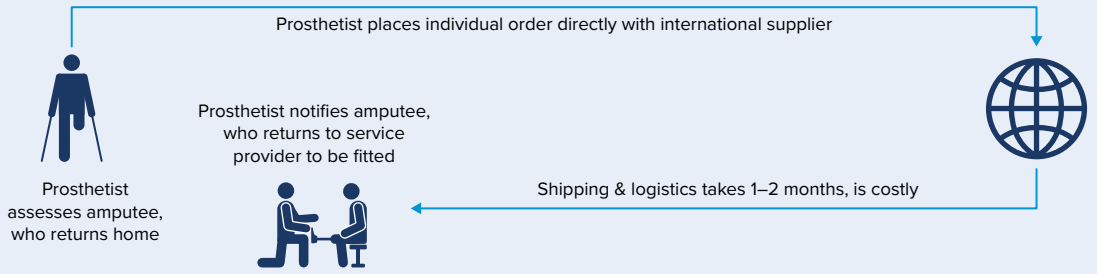
ANNEX H: OVERVIEW OF SELECT NOVEL SOCKET FABRICATION TECHNOLOGIES WITH POTENTIAL FOR ADOPTION IN LMICS

COMPANY	PRODUCT/INNOVATION	COMMERCIAL STATUS
Amparo (Est. 2014) **Germany** **www.amparo.world**	**Confidence Socket (BK)**: Thermoplastic direct-fitted on residual limb in 2 hours. Can be remoulded up to 10 times. Each socket arrives structurally formed and needs to be heated to be moulded to the residual limb. Fitted on-site with a mobile tool set that can be transported outside the prosthetic service unit and bypasses the need for orthopaedic workshop equipment and machinery.	• Commercially available in Europe, North America and Asia. • Acceptability pilot/clinical trial in Kenya: results expected in 2020.
Össur (Est. 1971) **Iceland** **www.ossur.asia/prosthetic-solutions/products/post-op-solutions/direct-socket-tool-kit**	**Össur Icecast:** Uses air pressure to mould the socket directly on the residual limb without orthopaedic workshop machinery. The pressure casting system loads the residual limb with even pressure, eliminating the need for modification of the socket shape. Carbon fibre and resin hardens to form the final socket.	• Commercially available globally. • Clinical studies have been conducted in South Africa and Indonesia to show it performs on a par with traditional sockets, but comfort issues arise due to liner sores. • Durable and efficient, but 5-6x the cost of traditional sockets.
Prosfit (Est. 2013) **Bulgaria** **www.prosfit.com**	**PandoFit:** End-to-end solution that enables cost-effective building of prosthetic service provision capacity. Combines 3D scanning (which creates a digital scan of the limb) with cloud-based and/or offline rectification software to design sockets. Socket is 3D printed via a global network of certified 3D manufacturing partners (currently a non-exclusive partnership with HP) which allows delivery of products with consistent quality. The socket is printed with PA12 Nylon and is 1kg lighter than traditional designs.	• Commercially available globally. • Sockets meet ISO standards and are regulated as medical devices in Europe, Australia, and Singapore • Clinical investigation conducted in 2015. • Clinical trials in Syria, Togo, and Madagascar in 2016 showed viability of solution and to improve prosthetist productivity; albeit cost of 3D printing is much higher than traditional socket fabrication methods and not yet economically feasible. • Trial in Middle East in 2018-2019 combined telehealth approaches and PandoFit that enabled task-shifting to local physiotherapists to fit 40 amputees in a challenging environment. • Prosfit is launching a capacity building project in East Africa that offers training on the PandoFit solution, infrastructure development, tele-health, data collection, and policy recommendations. First phase is estimated to fit 200-250 users and will cost EUR 0.5-EUR 1 million.

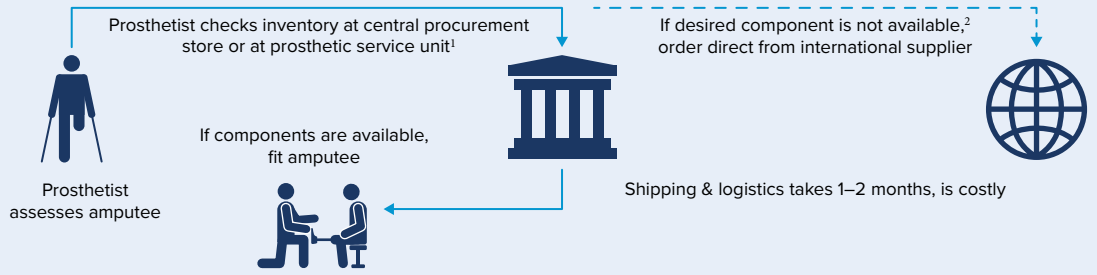
COMPANY	PRODUCT/INNOVATION	COMMERCIAL STATUS
Nia Technologies (Est. 2015) **Canada** **www.niatech.org**	**3D PrintAbility:** On-site digital toolchain used to 3D print lower-limb prosthetics and orthotics. The toolchain includes: 3D scanner, NiaFit rectification software, and 3D printer. Prosthetic sockets can be printed in 5-8 hours using polypropylene material.	• Commercially available and currently recruiting early adopters. • Clinical trials in Cambodia, Uganda, and Tanzania show performance and acceptability on a par with ICRC sockets. However, issues with socket cracking and discomfort caused by (previous version) material. • Nia is a non-profit social enterprise. Currently forming a new for-profit company and seeking investors to commercialise NiaFit software in developed countries.

ANNEX I: DIFFERENT COMPONENT SUPPLY CHANNELS OBSERVED IN LMICS[46]

FULFILLMENT #1: INDIVIDUAL ORDERS FROM INTERNATIONAL SUPPLIER

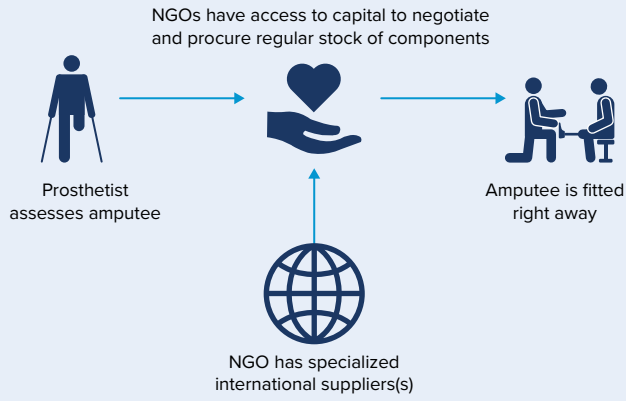


FULFILLMENT #2: PUBLIC SECTOR

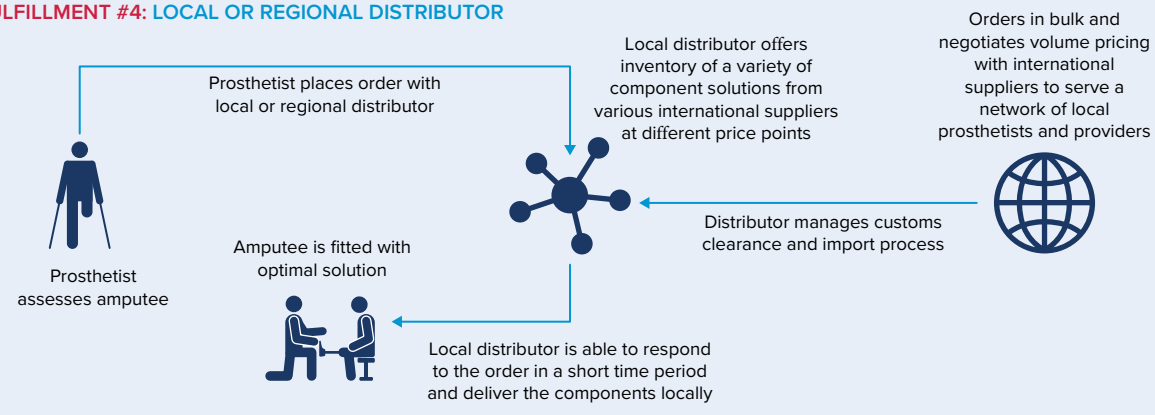


[1] Because central and provider procurements are made annually or periodically, it can be difficult to predict demand and stock the desired components. Components may not have a long shelf life and bulk orders can also be delayed due to processing of order or customs challenges.
[2] Alternatively, if desired components are not available, sub-optimal components that are available in stock may be chosen instead.

FULFILLMENT #3: NGO



FULFILLMENT #4: LOCAL OR REGIONAL DISTRIBUTOR



[46] Diagrams from CHAI, based on CHAI expert consultations.

ATscale

GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY

THIS REPORT WAS DELIVERED UNDER THE AT2030 PROGRAMME, FUNDED BY UK AID.

AT2030

UKaid

from the British people